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IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

ORTHO PHARMACEUTCAL CORP.,

Petitioner,

—v.—

GENETICS INSTITUTE, INC. and AMGEN, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the holder of an exclusive license to practice a patent in a particular field-of-use has standing to seek damages for infringing acts within its designated field-of-use, where the patent owner is joined as a party.

2. Whether standing for an exclusive field-of-use licensee to sue for infringement within its designated field-of-use is measured by the exclusivity of its rights with respect to the *entirety* of the "use" right covered by the patent, or by the exclusivity of its rights within the *particular* field-of-use.

LIST OF PARTIES

The names of all parties to the proceeding in the court whose judgment is sought to be reviewed are the parties listed in the caption of this Petition.

STATEMENT PURSUANT TO RULE 29.1

Petitioner Ortho Pharmaceutical Corp. ("Ortho") is a subsidiary of Johnson & Johnson. Ortho does not have any subsidiaries or affiliates that have issued shares to the public.

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PETITION FOR A WRIT OF CERTIORARI TO
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PETITION FOR WRIT OF CERTIORARI

Ortho Pharmaceutical Corp. ("Ortho") requests that this Court issue a writ of certiorari to review the opinion of the United States Court of Appeals for the Federal Circuit entered on April 5, 1995.

OPINIONS BELOW

The decision of the U.S. Court of Appeals for the Federal Circuit is reported at 52 F.3d 1026, and is reproduced as Appendix A hereto. The district court decision dismissing Ortho's complaint for lack of standing is reported *sub nom. Amgen, Inc. v. Chugai Pharmaceutical Co.*, 808 F. Supp. 894 (D. Mass. 1992), and is reproduced as Appendix B.

The Report and Recommendation of Magistrate Saris, dated May 5, 1989, recommending denial of Ortho's motion to intervene in the liability phase of an action captioned *Amgen, Inc. v. Chugai Pharmaceutical Co.* (hereafter, *"Amgen v. Chugai"*), is unreported and is reproduced as Appendix C. The order of the district court, dated May 26, 1989, approving the Magistrate's report and recommendation on Ortho's motion to intervene in the liability phase of the *Amgen v. Chugai* case and denying the motion to intervene, is unreported and is reproduced as Appendix D. The order of the district court consolidating this action with the *Amgen v. Chugai* case is unreported and is reproduced as Appendix E. The order of the district court rescinding the consolidation of this case with *Amgen v. Chugai,* which order was entered in response to Ortho's motion to certify the order dismissing this case for appeal pursuant to Rule 54(a), Fed.R.Civ.P., is unreported and is reproduced as Appendix F.

STATEMENT OF JURISDICTION

Jurisdiction in this Court is based upon 29 U.S.C. § 1254(a). The decision and judgment of the U.S. Court of Appeals for the Federal Circuit was entered April 5, 1995, and is printed herein as Appendix A.

STATUTES INVOLVED IN THE CASE

35 U.S.C. 281: " A patentee shall have remedy by civil action for infringement of his patent."

35 U.S.C. 284, ¶ 1: "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer together with interest and costs as fixed by the court."

STATEMENT OF THE CASE

This case presents an important question concerning standing by exclusive licensees to sue for patent infringement: Whether the holder of an exclusive license to practice a patent in a particular field-of-use has standing to sue for acts of infringement in that field-of-use, where the patent owner is joined as a party. It also presents the question of whether the measure of standing for the holder of such a license is: (a) the exclusivity of its rights with respect to the *entirety* of the "use" right covered by the patent (which was the approach taken by the Federal Circuit in this case), or (b) the exclusivity of its rights with respect to the *particular field-of-use* where the acts of infringement occurred.

Until the Federal Circuit's decision in this case, it was settled law that exclusive licensees have standing to sue for acts of infringement in their designated field-of-use, provided that the license confers exclusive rights in that particular field, and provided further that the patent owner is joined as a party. This Court so held in *Independent Wireless Telegraph Co. v. Radio Corp. of America*, 269 U.S. 459 (1926).

The Federal Circuit's decision is in direct conflict with this Court's decision in *Independent Wireless*, and effectively overrules it. It does this by making standing for an exclusive field-of-use licensee depend on whether the license confers exclusive rights in the *entirety* of the "use" rights covered by the patent. The problem with this approach is that a field-of-use license, by definition, confers rights only in a particular field and not in the *entirety* of the "use" right. Thus, the Federal Circuit's approach makes it impossible for the holder of an exclusive field-of-use license to sue for infringing acts in its designated field-of-use.

The consequences of the Federal Circuit's decision go beyond the geographical boundaries of any regional circuit. Because all appeals in patent cases are heard by the Court of Appeals for the Federal Circuit, the Federal Circuit's decision changes the law for all patent cases throughout the country. Unless this Court grants certiorari, its decision in *Independent Wireless* will have been effectively overruled, as a matter of uniform national law.

A. The Nature Of This Action

In this action, Ortho seeks damages from Genetics Institute for its infringement of U.S. Patent No. 4,703,008 (the "'008 patent"). The '008 patent covers a DNA sequence and transfected host cells that are used to make a hormone known as erythropoietin or "EPO." EPO stimulates the body's production of red blood cells. Recombinant EPO is widely used to treat anemia.

Ortho holds an exclusive license to use the '008 invention in the United States, *inter alia*, to make EPO, in the United States, for use and sale everywhere in the world outside the United States (excluding China and Japan).

The field-of-use covered by Ortho's license is the same field-of-use where Genetics Institute committed its infringing acts. Those acts consisted of Genetics Institute's use of the patented invention in the United States, to make EPO in the United States, for use and sale in Europe. *Thus, Ortho has an exclusive license to use the '008 invention in the very same field-of-use where Genetics Institute's acts of infringement took place.*

Genetics Institute's infringing acts deprived Ortho of the exclusivity to which Ortho is entitled in its field-of-use,

and deprived Ortho of profits it could have earned but for the acts of infringement.

B. Factual Background

1. Ortho's Field-Of-Use License

Ortho's exclusive right to use the '008 invention in the United States to make EPO in the United States for use and sale abroad derives from a license agreement that Ortho entered into with Amgen, Inc. ("Amgen") in 1985. At the time, Amgen owned the application for the patent that later issued as the '008 patent.

The Ortho/Amgen License Agreement divides the entirety of the right to use the '008 technology in the United States into two portions: (a) the right to use the '008 technology to make EPO in the United States, for use and sale *within* the United States, and (b) the right to use the '008 technology to make EPO in the United States, for use and sale *outside* the United States (excluding China and Japan).

The License Agreement gives Ortho the exclusive right to use the '008 technology to make EPO in the United States, for use and sale *outside* the United States (excluding China and Japan).[1] (A 144). Amgen did not retain any right to use the '008 technology in this field-of-use. Nor did it retain the right to grant further licenses to third-parties in this field-of-use.

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[1] The License Agreement also gives Ortho certain rights to use the '008 technology, in the United States, to make EPO for use and sale *within* the United States. (A 144).

Under the terms of the License Agreement, Ortho is thus the only entity entitled to use the '008 invention, in the United States, to make EPO in the United States, for use and sale everywhere in the world outside the United States (excluding China and Japan).

2. Genetics Institute's Infringing Acts

Notwithstanding Ortho's exclusive license, Genetics Institute has used the '008 invention in the United States to make EPO in the United States for shipment to its European licensee, Boehringer Mannheim GmbH, for use and sale in Europe. Thus, Genetics Institute has used the '008 invention in the very same field-of-use where Ortho has exclusive rights.

Genetics Institute's use of the '008 invention for that purpose, in the United States, was not authorized, and it constitutes infringement of the '008 patent.

These acts of infringement in Ortho's field-of-use directly injured Ortho, depriving Ortho of its exclusive right to be the only manufacturer of EPO in the United States for use and sale abroad. Genetics Institute was paid more than $34 million by Boehringer Mannheim for the EPO it produced in the United States by its infringing acts in Ortho's exclusive licensed field.

C. Procedural History

1. Amgen's Infringement Action Against Chugai and Genetics Institute

When the '008 patent issued in 1987, Amgen brought suit against Genetics Institute and Chugai Pharmaceutical Co., Ltd., for infringing that patent. That suit was brought in the U.S. District Court for the District of Massachusetts, and was

captioned *Amgen, Inc. v. Chugai Pharmaceutical Co., et al.* (hereafter, *"Amgen v. Chugai"*). The district court bifurcated the *Amgen v. Chugai* case into separate phases for liability and damages, with the liability phase to be tried first.

Ortho sought leave to intervene in *Amgen v. Chugai* before either the liability or damage phase was tried. The district court denied Ortho's motion on the grounds that: (a) Amgen could adequately protect Ortho's rights with respect to *liability*, and (b) intervention could delay the upcoming trial in the *liability phase*. The Court did not address Ortho's right to intervene in the damage phase, once the liability phase ended.

Although the district court found that Amgen could adequately protect Ortho's rights with respect to *liability*, it never made a finding that Amgen could adequately protect Ortho's rights with respect to *damages*. Nor could it have made such a finding. Amgen has never even *attempted* to protect Ortho's rights with respect to damages. In fact, Amgen has done precisely the opposite: It has tried to usurp the damages attributable to Genetics Institute's infringement in Ortho's exclusive licensed field.

The liability phase of the *Amgen v. Chugai* case proceeded to trial before a magistrate in 1989. Upon conclusion of that trial, the district court held that the '008 patent is valid and enforceable, and was infringed by Genetics Institute. The Federal Circuit affirmed these findings in a decision that is reported at 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

2. Consolidation Of This Case With *Amgen v. Chugai*

Shortly after the Federal Circuit's decision concerning Genetics Institute's infringement of the '008 patent, Ortho commenced this action in the U.S. District Court for the District of Massachusetts. In this action, Ortho seeks damages for the injury it suffered as a result of Genetics Institute's infringing acts in Ortho's exclusive licensed field. As required under this Court's decision in *Independent Wireless Telegraph Co. v. Radio Corp. of America*, 269 U.S. 459, Ortho named the patent owner, Amgen, as a party in this action.

After commencing this action, Ortho promptly sought -- and obtained -- an order consolidating this action with the *Amgen v. Chugai* case. (Appendix E hereto). As a result of the consolidation order, all claims against Genetics Institute for damages based on its infringement of the '008 patent were subject to joint discovery in one consolidated action, and could be resolved in a single trial.

3. The District Court's Decision On Standing

Before answering the complaint, Genetics Institute moved to dismiss this action. Its theory was that Ortho was a "mere licensee," and therefore lacked standing to sue for infringement of the '008 patent. Seeking to usurp Ortho's rightful damages, Amgen joined in that motion.

In deciding the standing motion, the district court recognized that under this Court's decision in *Independent Wireless*, exclusive licensees are entitled to sue for infringing acts in their particular field-of-use. Thus, the district court stated:

> "An exclusive licensee generally has standing to sue for infringement against anyone operating without the stated authority in the stated area of exclusivity."

Amgen v. Chugai, 808 F. Supp. at 899 (App. B at B10-11) (quoting D. Chisum, *Patents*, § 21.03[2][c] at 21-157 [1991]). The district court also recognized that for standing purposes under *Independent Wireless*, an exclusive license "can be created by a grant of exclusivity based solely on . . . field-of-use limitations." *Amgen v. Chugai*, 808 F. Supp. at 900 (App. B at 12).

Consistent with *Independent Wireless*, the district court next analyzed whether Ortho's rights in its designated field are exclusive. It found that Ortho does indeed have an exclusive license in a particular field-of-use -- that field being use of the '008 invention in the United States, for the purpose of making EPO in the United States, for sale everywhere in the world outside the United States (excluding China and Japan). Thus, the district court stated:

> [Ortho holds] an "exclusive license" to use the invention claimed in the '008 patent for the manufacture of EPO . . . in the U.S. . . . for use sale outside the U.S. (excluding China and Japan).

Amgen v. Chugai, 808 F. Supp. at 902 (App. B at B-16). The district court also found that:

> [The License Agreement] clearly . . . precludes Amgen from licensing to any third parties the right to manufacture EPO in the U.S. under the '008 patent for sale abroad.

Id. In addition, the district court found that Genetics Institute's infringing acts had occurred in Ortho's exclusive field-of-use. *Id.*, 808 F. Supp. at 897 (App. B at B-6).

These findings are unquestionably correct. Neither Amgen or Genetics Institute challenged them on appeal. These findings should have ended the standing inquiry, compelling the conclusion that Ortho has standing to sue for infringement in its exclusive field-of-use.

The district court, however, went on to deny Ortho standing. The basis for this conclusion was a bizarre and unprecedented theory -- that a field-of-use license which "grants an exclusive license to use the inventions claimed in the '008 patent . . . in the U.S. to make an unpatented product (EPO) for sale abroad" somehow "exceeds the scope of the . . . patent," and therefore cannot provide a basis for standing. *Amgen v. Chugai*, 808 F. Supp. at 904 (App. B at B-21).

This theory appears to confuse the threshold issue of standing with the affirmative defense of patent misuse. The patent misuse doctrine permits an accused infringer to assert, by way of affirmative defense, that a patent owner's rights are unenforceable because the patent owner has required its licensees to accept license terms with anticompetitive effects "extending beyond the patentee's statutory right to exclude."[2]

However, the patent misuse doctrine -- like any affirmative defense -- only comes into play after the issue of standing is resolved (if it comes into play at all). It has no place whatsoever in the standing inquiry, just as other affirmative defenses have no bearing on whether a particular

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2 *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992).

plaintiff has standing to sue. The district court erred in confusing the standing issue with the entirely separate issue of whether Ortho's field-of-use license somehow "exceeds the scope of the '008 patent." *Amgen v. Chugai*, 808 F. Supp. at 904 (App. B at B-20).

The district court then compounded that error by concluding that Ortho's field-of-use license does indeed "exceed" the scope of the '008 patent. *Id.* This conclusion was wrong as a matter of law, and the Court of Appeals, quite sensibly, did not endorse it. Ortho's license, to use the patented invention in the United States for a particular purpose, covers a significant *part* of the proprietary "use" right conferred by the '008 patent. But it does not cover *more* than that right, and it does not in any way "exceed" the scope of the patent.

Moreover, even a license that extends beyond the patentee's statutory right to exclude does not render patent rights unenforceable absent proof of "anticompetitive effects" extending beyond the patentee's statutory right to exclude.[3] There was no evidence whatsoever that Ortho's field-of-use license has "anticompetitive effects."

4. Ortho's Motion For Rule 54(a) Certification

After the district court dismissed Ortho's complaint, Ortho moved in the district court for an order certifying the decision for appeal under Rule 54(a), Fed.R.Civ.P. Ortho filed its Rule 54(a) motion because the law in the Federal Circuit was not settled as to whether an order dismissing one of several

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[3] *Mallinckrodt*, 976 F.2d at 708.

consolidated actions is a final, non-interlocutory order that is appealable absent Rule 54(a) certification.[4]

In response to Ortho's motion for Rule 54(a) certification, the district court eliminated any need for certification by rescinding its prior order consolidating this case with the *Amgen v. Chugai* action. This removed any possible barrier to an appeal by Ortho. *See* Appendix E hereto.

5. The Federal Circuit's Decision

The Federal Court affirmed the district court's decision in an opinion which is reported at 52 F.3d 1026. The Federal Court did not adopt the rationale adopted by the district court. But it took an approach that was equally unprecedented and incorrect. The Federal Circuit effectively overruled this Court's decision in *Independent Wireless.*

Under *Independent Wireless*, whether a field-of-use licensee has standing depends on whether its rights are exclusive *in the particular field-of-use* where the acts of infringement took place. The Federal Circuit, however, never addressed the exclusivity of Ortho's rights *in its designated field-of-use*. Instead, it made Ortho's standing depend on exclusivity with respect to the *entirety* of the "use" right conferred by the patent -- something that field-of-use licensees

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[4] *Compare Kraft, Inc. v. Local Union 327, Teamsters*, 683 F.2d 131, 133 (6th Cir. 1982) (holding that a judgment in one of several consolidated actions is final and appealable), with *Huene v. United States*, 743 F.2d 703, 705 (9th Cir. 1984) (reaching the opposite conclusion). *See also, Hageman v. City Investing Co.*, 851 F.2d 69, 71 (2d Cir. 1988) (collecting cases).

never have. *See, Ortho v. Genetics Institute*, 52 F.3d at 1034 (App. A at A-16).

In addressing the exclusivity of Ortho's rights under the '008 patent, the Federal Circuit started by demolishing a straw man. It stated that "Ortho's right *to sell unpatented EPO abroad* . . . [is] not a proprietary right arising under the '008 patent." *Id.*, 52 F.3d at 1033 (App. A at A-15) (emphasis added). That is correct but irrelevant, since the *sale* of unpatented EPO is *not* the field-of-use where Genetics Institute's infringing acts took place, and it is not the field-of-use that provides the basis for Ortho's standing.

The Federal Circuit also stated that "Ortho's right *to use the '008 invention at one location in the United States"* is "nonexclusive." *Id.*, 52 F.3d at 1034 (App. A at A-16) (emphasis added). But an *unparticularized* right to "use the '008 invention at one location in the United States," *id.*, once again, is *not* the proprietary field-of-use right that gives Ortho standing.

The right that *does* give Ortho standing is an exclusive field-of-use right, under the '008 patent, to *use the '008 invention in the United States for the purpose of making EPO in the United States, for use and sale everywhere in the world outside the U.S. (excluding China and Japan).* It is undisputed that Ortho has exclusive rights in this particular field-of-use. The district court so found,[5] and its findings were not challenged on appeal.

By allowing an exclusive licensee to have standing only if its license confers an exclusive right to use the patented

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[5] *Amgen v. Chugai*, 808 F. Supp. at 902 (App. B at B-16).

invention *in general*, the Federal Circuit decision makes it impossible for the holder of an exclusive field-of-use license *ever* to have standing to sue for acts of infringement in its exclusive licensed field. That result cannot be reconciled with this Court's decision in *Independent Wireless*.

REASONS FOR GRANTING THE WRIT

I. The Federal Circuit's Decision Conflicts with Decisions of This Court and of Other Circuits

This Court held in *Independent Wireless Telegraph Co. v. Radio Corp. of America*, 269 U.S. 459 (1926), that the holder of an exclusive license has standing to sue for acts of patent infringement in its designated field-of-use, provided that its rights *in that particular field* are exclusive and provided further that the patent owner is also a party.

Following *Independent Wireless*, lower cases were unanimous in holding that an exclusive license in a particular field-of-use is sufficient to confer standing. *See, e.g.:*

-- *Western Electric Co., Inc. v. Pacent Reproducer Corp.*, 42 F.2d 116 (2d Cir. 1930) (holding that an exclusive field-of-use license to use a patented invention only for production of sound records was a sufficient basis for standing);

-- *Brunswick Corp. v. United States*, 19 USPQ2d 1702 (Ct. Cl. 1991) (holding that an exclusive field-of-use license to manufacture and sell patented camouflage material only for one

particular customer was a sufficient basis for standing);

- *Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc.*, 222 USPQ 143 (D. Kan. 1983) (holding that an exclusive field-of-use license to use a patented invention only in the veterinary field was a sufficient basis for standing);

- *Pratt & Whitney Co. v. United States*, 153 F. Supp. 409, 114 USPQ 246 (Ct. Cl. 1957) (holding that an exclusive field-of-use license to use a patented invention only with engines in aircraft and guided missiles was a sufficient basis for standing).

Until this case, we are not aware of *any* decisions denying the holder of an exclusive field-of-use license standing to sue for infringing acts in its exclusive licensed field, where, as here, the patent owner is also a party.

This case departs from this previously unbroken line of precedent. Contrary to *Independent Wireless* and the field-of-use cases following it, the Federal Circuit made standing for an exclusive field-of-use licensee depend on the exclusivity of its rights with respect to the *entirety* of the "use" right. *Ortho v. Genetics Institute*, 52 F.3d at 1034 (App. A at A-16).

The Federal Circuit's approach is in direct conflict with *Independent Wireless* and its progeny. Under *Independent Wireless*, the test of standing for a field-of-use licensee is exclusivity *within the particular field-of-use* where the acts of infringement occurred. The test is not -- and cannot be -- exclusivity of the license with respect to the *entirety* of the "use" right.

By definition, holders of exclusive field-of-use licenses have not been granted exclusivity for the *entirety* of the "use" right. Making standing for holders of such licenses depend on exclusivity in the *totality* of the "use" right, as the Federal Circuit has done, would leave exclusive field-of-use licensees unable to sue for infringement in their particular field-of-use. That result is directly contrary to *Independent Wireless*, and effectively overrules it.

Because the Federal Circuit hears all appeals in patent infringement cases, other circuits will not have any opportunity to address this issue. Unless this Court grants Ortho's petition for a writ of certiorari, the Federal Circuit's approach will be followed in patent infringement cases throughout the country, and exclusive field-of-use licensees will no longer have the standing that they are entitled to under *Independent Wireless*.

II. Allowing Exclusive Field-Of-Use Licensees to Sue for Infringement In Their Designated Fields-Of-Use Is "Indispensible"

This Court has previously recognized the importance of the issues presented by this case. As this Court emphasized in *Independent Wireless*, permitting an exclusive field-of-use licensee to sue for infringement in its exclusive licensed field is "indispensable to the enjoyment by the [exclusive] licensee of the monopoly" which it has been given under the terms of the license. *Id.*, 269 U.S. at 469.

Exclusive licenses, which provide a basis for standing under this Court's prior decisions, are different in their basic nature from non-exclusive licenses, which do not have that effect. A non-exclusive license is merely a grant of permission to practice the patent in a given area without being sued for

infringement; it does not carry with it any promise that the patent owner will refrain from giving the same permission to third-parties. Thus, the holder of a non-exclusive license has every reason to expect that other parties will practice the patent in the area of its license -- and has no basis for complaint in the event a third-party does so.[6]

In contrast, an exclusive license is much more than a mere permission to practice the patent in a given field. It is a binding promise that the same permission will not be given to anyone else. Thus, it gives the exclusive licensee a justified expectation that no one else will share its rights to practice the patent. In this sense, the exclusive licensee, like the patent owner, enjoys a legally protected "monopoly," *Independent Wireless*, 269 U.S. at 469, in its designated area of use. Its rights -- in being the only one who can practice the patent in the area covered by license -- thus come "close to . . . truly proprietary interests in the patent . . ." *Philadelphia Brief Case Co. v. Specialty Leather Products Co.*, 145 F. Supp. 425, 428 (D.N.J. 1956), *aff'd*, 242 F.2d 511 (3d Cir. 1957). Under *Independent Wireless*, the measure of that protectible interest is exclusivity in the area of use where the infringing acts occur.

If a third-party practices the patent in the area covered by an exclusive license, the holder of the exclusive license is deprived of precisely the exclusivity that its license is meant to confer. The effect is the same as if the patent owner violated the promise of exclusivity by granting additional licenses in the area covered by the exclusive license.

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6 *See, Waterman v. McKenzie*, 138 U.S. 252 (1891); *Schneider (Europe) AG v. SciMed Life Systems, Inc.*, 28 USPQ2d 1225, 1229 (D.Minn. 1993).

In such circumstances, the exclusive licensee is the party "directly injured" by the acts of infringement in its exclusive licensed field.[7] To be sure, the licensor may be injured indirectly, through the loss of royalties it might otherwise receive from its exclusive licensee. But it is the holder of an exclusive license whose exclusive rights are directly invaded, and indeed destroyed, by reason of infringing acts in the area of its license.

Permitting the patent owner, and not the exclusive licensee, to recover the damages attributable to infringing acts within the exclusive licensed field would, in effect, reward patent owners who acquiesce in acts of infringement by giving them, and not the exclusive licensee, the damages for that infringement.

Until this case, courts have not permitted this inequitable result. They have recognized that the holder of an exclusive license may sue for infringing acts in its licensed field, provided that the patent owner is also a party. *See, e.g., Independent Wireless*, 269 U.S. 459; *Waterman v. McKenzie*, 138 U.S. 252.[8]

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[7] *Duplan Corp. v. Deering Milliken Research Corp.*, 522 F.2d 809, 814 (4th Cir. 1975).

[8] *See also, Weinar v. Rollform, Inc.*, 744 F.2d 797, 807 (Fed. Cir. 1984), *cert. denied*, 470 U.S. 1084 (1985) (party with exclusive right to distribute in the United States may be joined with the patent owner; "two parties sharing the property rights represented by a patent may have their respective rights protected by injunction and each, when properly joined in a suit, may be entitled to damages."); *Duplan Corp. v. Deering Milliken Research Corp.*, 522 F.2d 809 (4th

Because the licensor and the exclusive licensee suffer injuries that are different in kind, courts have also recognized that the "measure of damages" should be different for each.[9] In cases where the licensor's only injury is the loss of royalties it otherwise would have received from its exclusive licensee, the damages "adequate to compensate" the licensor for the infringement, 28 U.S.C. § 284, would not exceed the bare minimum recoverable under the patent statute, *i.e.*, a "reasonable royalty." *Id.* In contrast, the injury to the holder of an exclusive license -- and its recoverable damages -- may be much greater. For the exclusive licensee, the damages "adequate to compensate for the infringement," 35 U.S.C. § 284, may include lost profits in an amount exceeding the royalties that the licensor has lost.

If parties holding exclusive licenses were not allowed to recover for their injury, infringers would escape responsibility for the full measure of damages caused by their wrongful acts.

Cir. 1975); *Jeoffroy Mfg. Inc. v. Graham*, 206 F.2d 772 (5th Cir. 1953), *cert. denied*, 337 U.S. 920 (1954); *Site Microsurgical Systems, Inc. v. Cooper Companies, Inc.*, 797 F. Supp. 333, 337 (D. Del. 1992); *Calgon Corp. v. Nalco Chemical Co.*, 726 F. Supp. 983, 988 (D. Del. 1989) ("The exclusive licensee should, in equity, be able to commence an action for infringement when the patent owner refuses to vindicate his rights."); *Dreamlite Holdings Ltd. v. Kraser*, 9 USPQ2d 1401, 1403 (E.D.N.Y. 1988), *aff'd*, 878 F.2d 1446 (Fed. Cir. 1989)(unpublished); *Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc.*, 565 F. Supp. 931.

[9] *See, e.g., Cold Metal Process Co. v. E.W. Bliss Co.*, 285 F.2d 231, 240-41 (6th Cir. 1960).

Duplan, 522 F.2d at 815. That result would be inconsistent with the basic purposes of the patent laws.

Under *Independent Wireless*, the principles discussed above are fully applicable to field-of-use licenses, which confer rights in a *portion* (but not the entirety) of the overall right to make, use or sell that is covered by the patent grant. Field-of-use licenses are a common feature of patent licenses.

The practice of granting field-of-use licenses has long been recognized and approved by courts. *See, e.g., General Talking Pictures Corp. v. Western Electric Co.*, 304 U.S. 175, *aff'd on rehearing*, 305 U.S. 124 (1939). As this Court stated more than half a century ago:

> The practice of granting licenses for a restricted use is an old one . . . . So far as appears, its legality has never been questioned.

Id., 305 U.S. at 127. Following *General Talking Pictures*, lower courts have approved of field-of-use licenses in an unbroken line of cases.[10]

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[10] *See, e.g.*: *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1126 (D.C.C. 1981); *Armstrong v. Motorola, Inc.*, 374 F.2d 764, 774 (7th Cir.), *cert. denied*, 389 U.S. 830 (1967); *Barr Rubber Products Co. v. Sun Rubber Co.*, 277 F. Supp. 484, 506 (S.D.N.Y. 1967), *modified on other issues*, 425 F.2d 1114 (2d Cir.), *cert. denied*, 400 U.S. 878 (1970); *Westinghouse Electric Corp. v. Bulldog Electric Products Co.*, 106 F. Supp. 819 (D.W.Va. 1952), *aff'd*, 206 F.2d 574 (4th Cir.), *cert. denied*, 346 U.S. 909 (1953); *Q-Tips, Inc. v. Johnson & Johnson*, 109 F. Supp. 657 (D.N.J. 1951), *aff'd*, 207 F.2d 509

The factors that justify standing for exclusive licensees apply with full force where the license confers exclusivity in a particular field-of-use. Like the patent owner itself, the holder of an exclusive field-of-use license enjoys a justified expectation that third-parties will not practice the patent in the designated area of use. Like the patent owner, the holder of such a license is entitled to exclusive enjoyment of proprietary rights conferred by the patent in a particular area. Acts of infringement in its designated field-of-use destroy the exclusive rights that its license is meant to confer, and cause direct injury in the designated field-of-use. Permitting the holder of such a license to sue for infringing acts in their field-of-use is thus "indispensable" to the enjoyment of the exclusive rights it has been given. *Independent Wireless*, 269 U.S. at 469.

Until the Federal Circuit's decision in this case, the law was clear that field-of-use licensees were entitled to sue for acts of infringement in their designated area of use, provided that their rights in the particular field-of-use are exclusive and provided further that the patent owner is named as a party.

The Federal Circuit's decision in this case is a departure from that previously unbroken line of authority. The decision establishes a dangerous precedent. It leaves parties holding exclusive field-of-use licenses without a remedy for the direct injury they suffer by reason of infringing acts in their designated fields-of-use. It thereby diminishes the value of field-of-use licenses, and indirectly, of patents themselves. It should be reviewed on certiorari.

(3d Cir. 1953), *cert. denied*, 347 U.S. 935 (1954).

CONCLUSION

For the reasons set forth above, this Court should grant Ortho's petition for a writ of certiorari.

Dated: July 5, 1995

Respectfully submitted,

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93-1166

ORTHO PHARMACEUTICAL CORP.,

Plaintiff-Appellant,

and

CILAG GESELLSCHAFT M.B.H., CILAG N.V.,
CILAG LTD., CILAG S.A.R.L., CILAG G.M.B.H.,
CILAG S.P.A., CILAG MEDICAMENTA, LDA.,
JOHNSON & JOHNSON S.A. (CILAG DIVISION),
CILAG AB, CILAG AG AND CILAG AG INTERNATIONAL,

Plaintiffs,

v.

GENETICS INSTITUTE, INC.
and AMGEN, INC.,

Defendants-Appellees.

DECIDED: April 5, 1995

Before ARCHER, Chief Judge, NIES* and MICHEL, Circuit Judge.

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* Circuit Judge Nies vacated the position of Chief Judge on March 17, 1994.

NIES, Circuit Judge.

This appeal raises a question of a patent licensee's standing to sue an infringer in the name of the patentee/licensor. Ortho Pharmaceutical Corporation is a licensee of Amgen, Inc., owner of United States Patent No. 4,703,008 (the '008 patent). Ortho and its sublicensees filed suit against Genetics Institute for infringement of the '008 patent in the District Court for the District of Massachusetts. The district court dismissed Ortho's suit concluding that Ortho was a nonexclusive licensee and, therefore, lacked standing. Ortho Pharmaceutical Corp. v. Genetics Institute, Inc., Civil Action 91-12174-Y (D. Mass. Dec.4, 1992) (judgment) (reported sub nom. Amgen, Inc. v. Chugai Pharmaceutical Co., 808 F. Sup.. 894, 27 USPQ2d 1578). We affirm.

I.

The '008 patent claims a product used for the production of erythropoietin (EPO), a hormone that stimulates the synthesis of red blood cells in bone marrow. The '008 patent claims a purified and isolated DNA sequence encoding human EPO and host cells transformed or transfected with a DNA sequence in a manner allowing host cells to express EPO. The claims do not claim the EPO product itself.[1]

In 1984, three years prior to the issuance of the patent, Amgen and Kirin Brewery Company established a joint venture, Kirin-Amgen, Inc. At that time, Amgen, as owner of

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[1] For a full analysis of the invention, see Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 112 S. Ct. 169 (1991).

the then-pending application for the '008 patent, assigned certain rights to Kirin-Amgen. In 1985, Ortho entered into Product License Agreements (PLAs)[2] with Kirin-Amgen and Amgen separately under which Ortho was allowed limited rights to manufacture in the United States and sell EPO in the United States and in certain foreign counties in which the licensors were seeking to obtain patents on various products and processes, including EPO itself.

On October 27, 1987, the date the '008 patent issued, Kirin-Amgen assigned the patent to Amgen. On the same date, Amgen brought suit for infringement against Genetics and Chugai. The trial of Amgen's suit was bifurcated into liability and damages phases. Shortly before trial on liability, Ortho attempted to intervene under Fed. R. Civ. P. 24, either as a matter of right or permissively, based on its rights under the license from Amgen. This motion was denied on the grounds of untimeliness and because Ortho's interests were adequately represented by Amgen respecting liability, a decision Ortho did not appeal. Following a bench trial on liability, claims 2, 4, and 6 of the '008 patent were held not to be invalid or unenforceable and found to be infringed by both Chugai and Genetics Institute. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 USPQ2d 1737 (D. Mass. 1989). This court affirmed that judgment on interlocutory appeal. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d at 1200, 18 USPQ2d at 1016.

Ortho and its European sublicensees then filed a suit against Genetics Institute in the same court. Before an answer

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[2] In 1988, the PLAs replaced the Technological License Agreements, entered at the same time as the PLAs, upon approval in France of recombinant EPO for human use.

was filed, they amended the complaint to name Amgen as a defendant and subsequently moved to realign Amgen as an involuntary plaintiff. Genetics and Amgen filed motions to dismiss or for summary judgment on the ground of the plaintiff's lack of standing or for failure to state a claim. Ortho and the co-plaintiffs cross-moved to intervene in the Amgen litigation for the purpose of securing part of the damages. Ortho's suit was consolidated with the Amgen suit.

In reply to the defendants' motions, Ortho again asserted its rights as a licensee of Amgen. In particular, Ortho relied on Paragraph 2.01 of the PLA license, which provides:

> (a) AMGEN hereby grants to Ortho but not AFFILIATES, except as hereinafter provided, an exclusive license to make in one location, have made and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENSED TERRITORY.
>
> (b) AMGEN, having received the consent of Kirin Brewery Co., Ltd., hereby grants to ORTHO but not AFFILIATES, an exclusive license, except as against AMGEN's rights under this AGREEMENT in the LICENSED TERRITORY, to make EPO in one location in the United States for use and sale outside the LICENSED TERRITORY but not including China and Japan. AMGEN shall provide to ORTHO all information and any assistance and know-how required to ORTHO to achieve the purposes of this paragraph . . . .

The agreement defined the LICENSED TERRITORY as the United States and the LICENSED FIELD as "all indications

for human use except dialysis and diagnostics." In return, Amgen received royalties on Ortho's resulting sales of EPO in the United States.[3] Thus, one of the effects of paragraph 2.01(a), as interpreted by the court, was to grant Ortho the implied right to use the invention claimed in the '008 patent in one location to make EPO, for use or sale in the United States, for all human use except dialysis or diagnostics. Paragraph 2.01(b) repeated the implied grant to Ortho to use the '008 invention to make EPO in one location in the United States and, with Kirin-Amgen's consent, the right to make certain foreign sales of EPO.

The PLA executed by Ortho and Amgen also contains section 8.02 entitled "Infringement by Third Parties." Amgen argues that this section precludes Ortho's suit because Amgen exercised its right to sue alone, as provided therein. However, Ortho disputes that the provisions control to bar a second suit by Ortho in Amgen's name, even though Amgen has sued.

In ruling on the motion, the court first rejected Ortho's argument that it could premise standing based upon paragraph 2.01(a) of the license agreement. The court reasoned that because Amgen did not promise not to sublicense its own right to use its '008 invention to manufacture EPO in the United States, Ortho held a nonexclusive license under this provision. 808 F. Supp. at 902, 27 USPQ2d at 1584. The court also found no merit in Ortho's argument that paragraph 2.01(b) granted it an exclusive field-of-use license for sales of EPO abroad. The court emphasized that the '008 patent did not cover sales of EPO itself. Thus, Ortho's right to sell EPO

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[3] Ortho paid royalties to Kirin-Amgen on Ortho's European sales. As a licensee of European patents, Ortho has filed suit in European against Genetics' European customer.

abroad could not be a right arising from or a license under the U.S. patent grant. As in paragraph 2.01(a), Ortho's license to use the '008 patented technology was held to be nonexclusive. 808 F. Supp. at 904, 27 USPQ2d at 1585. The district court did not rule on the effect of the right to sue provisions in the contract. Upon entry of the judgment of dismissal, the trial judge vacated the order of consolidation with the Amgen litigation. This appeal followed. The sole issue on appeal is whether Ortho's license gave it standing to sue.

II.

The Patent Act of 1952 provides "a patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281 (1988). The term patentee includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." 35 U.S.C. § 100(d) (emphasis added). Thus, the statute requires that the parties to an infringement suit will have the patentee on one side and the accused infringer on the other. Without the patentee as plaintiff, the remedies provided in the patent statute are unavailable except in extraordinary circumstances "as where the patentee is the infringer, and cannot sue himself." Waterman v. Mackenzie, 138 U.S. 252, 255 (1891) (suit dismissed because not brought by record owner); Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 40-41 (1923) (plaintiff must have legal title to patent at the time of infringement);[4] see also Arachnid, Inc. v. Merit Indus., Inc.,

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[4] 35 U.S.C. § 261 Provides in pertinent part:

> Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or

939 F.2d 1574, 1579, 19 USPQ2d 1513, 1517 (Fed. Cir. 1991) (relying on Crown Die).

Courts look to the substance of an agreement to determine whether it has the effect of an assignment and, thus, satisfies the statutory requirement that the "patentee" must sue. Where a patentee makes an assignment of all significant rights under the patent, such assignee may be deemed the effective "patentee" under the statute and has standing to bring a suit in its own name for infringement. Vaupel Textilmaschinen KG v. Meccanca Euro Italia s.p.a., 944 F.2d 870, 875, 20 USPQ2d 1045, 1049 (Fed. Cir. 1991) (transfer of substantially all rights held to be assignment); Bell Intercontinental Corp. v. United States, 381 F.2d 1004, 1011, 152 USPQ 182, 184 (Ct. Cl. 1967); see Waterman, 138 U.S. at 260 (mortgagee held to be patent owner). Any other party seeking enforcement of the patent can sue, if at all, only with the patentee or in the name of the patentee. "Any rights of the licensee must be enforced through or in the name of the owner of the patent," and "never in the name of the licensee alone, unless that is necessary to prevent an absolute failure of

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> legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.
>
> . . . .
>
> An assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage.

justice." Waterman, 138 U.S. at 255; see Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459, 468 (1926) (patentee necessary to give jurisdiction in law or equity and to enable infringer to defeat all claims in one action or bar all other actions by satisfying one decree); Abbott Labs. v. Diamedix Corp., No. 94-1345, 1995 WL 50152 (Fed. Cir. Feb. 7, 1995) (patentee has a right to intervene in licensee's suit).

Saying that a licensee must sue with or in the name of the patentee does not mean that every licensee under a patent has a rightful place in an infringement suit. A licensee must have "standing" under the patent statute. A license may amount to no more than a covenant by the patentee not to sue the licensee for making, using or selling the patented invention, the patentee reserving the right to grant others the same right. A holder of such a nonexclusive license suffers no legal injury from infringement and, thus, has no standing to bring suit or even join in a suit with the patentee. As explained in Western Elec. Co. v. Pacent Reproducer Corp., 42 F.2d 116, 118 (2d Cir.), cert. denied, 282 U.S. 873 (1930);

> In it simplest form, a license means only leave to do a thing which the licensor would otherwise have a right to prevent. Such a license grants to the licensee merely a privilege that protects him from a claim of infringement by the owner of the patent monopoly . . . . He has no property interest in the monopoly of the patent, nor any contract with the patent owner that others shall not practice the invention. Hence the patent owner may freely license others, or may tolerate infringers, and in either case no right of the patent licensee is violated. Practice of the invention by others may indeed cause him pecuniary loss, but it does him no legal injury.

The district court here relied on Judge Hand's analysis of standing in A.L. Smith Iron Co. v. Dickson, 141 F.2d 3, 6 (2d Cir. 1944), with which we agree:

> The key question for determining standing of a licensee is whether the licensee as a matter of law has an exclusive property interest in the patent itself, not whether the licensee in fact has been harmed by a third-party infringer. As Judge Learned Hand explained in A.L. Smith Iron Co. v. Dickson, 141 F.2d 3, 6 (2d Cir. 1944), there are strong policy reasons why patent law does not confer standing on a nonexclusive licensee to sue a third party for infringement even though the licensee has suffered due to the infringement:
>
> > It is indeed true that a mere licensee may have an interest at stake in such a suit; his license may be worth much more to him than the royalties which he has agreed to pay, and its value will ordinarily depend on his ability to suppress the competition of his rivals. The reason why he is not permitted to sue is not because he has nothing to protect. But against that interest is the interest of the infringer to be immune from a second suit by the owner of the patent; and also the interest of the patent owner to be free to choose his forum . . . . Indeed, the owner may have granted a number of licenses, and it would be exceedingly oppressive to subject him to the will of all his licensees. These two interests in combination have been held to

> overweigh any interest of the licensee[.]

808 F. Supp. at 904 n.11, 27 USPQ2d at 1585 n.11.

Thus economic injury alone does not provide standing to sue under the patent statute. To have co-plaintiff standing in an infringement suit, a licensee must hold some of the proprietary sticks from the bundle of patent rights, albeit a lesser share of rights in the patent than for an assignment and standing to sue alone. See Weinar v. Rollform, Inc., 744 F.2d 797, 803, 223 USPQ 369, 374-75 (Fed. Cir. 1984) (exclusive licensee properly joined in suit; "two parties sharing the property rights represented by the patent may have respective rights protected").

The proprietary rights granted by any patent are the rights to exclude others from making, using or selling the invention in the United States.[5] A patent license may have the effect between the parties to the license of transferring some of those proprietary rights from the patentee to its licensee. Such license then does more than provide a covenant not to sue, i.e., a "bare" license. In addition, the license makes the licensee a beneficial owner of some identifiable part of the patentee's bundle of rights to exclude others. Thus, a licensee with proprietary rights in the patent is generally called an "exclusive" licensee. But it is the licensee's beneficial ownership of a right to prevent others from making, using or selling the patented

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[5] 35 U.S.C. § 154 states:

> Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, or selling the invention throughout the United States.

technology that provides the foundation for co-plaintiff standing, not simply that the word "exclusive" may or may not appear in the license. As stated in Philadelphia Brief Case Co. v. Speciality Leather Prods Co., 145 F. Supp. 425, 428, 111 USPQ 180, 182 (D.N.J. 1956), aff'd, 242 F.2d 511, 113 USPQ 100 (3rd Cir. 1957):

> [T]his so-called exclusive licensee, while only a licensee, comes so close to having truly proprietary interests in the patent, that the courts have held that he is equitably entitled to sue on the patent, provided he joins the true proprietor of the patent in such suit[.]

The consequence of recognizing co-plaintiff standing is that the licensee has a right to bring suit on the patent, albeit in the name of the licensor, whether or not the license so provides and regardless of the patentee's cooperation. Further, the patentee/licensor suffers the legal consequences of litigation brought in its name. As stated in Independent Wireless Co., 269 U.S. at 469:

> It seems clear then on principle and authority that the owner of a patent who grants to another the exclusive right to make, use or vend the invention, which does not constitute a statutory assignment, holds the title to the patent in trust for such a licensee, to the extent that he must allow the use of his name as plaintiff in any action brought at the instance of the licensee in law or in equity to obtain damages for the injury to this exclusive right by an infringer or to enjoin infringement of it. Such exclusive licenses frequently contain express covenants by the patent-owner and licensor to sue infringers that expressly cast upon the former the affirmative duty

> of initiating and bearing the expense of the litigation. But without such express covenants, the implied obligation of the licensor to allow the use of his name is indispensable to the enjoyment by the licensee of the monopoly which by personal contract the licensor has given. Inconvenience and possibly embarrassing adjudication in respect of the validity of the licensor's patent rights, as the result of suits begun in aid of the licensee, are only the equitable and inevitable sequence of the licensor's contract, whether express or implied. [Emphasis added.]

In the case at hand, the patentee has refused to let its licensee join in its suit against an infringer. However, co-plaintiff standing is determined by whether or not the licensee acquired proprietary rights in the patent under the contract with the patentee. The patentee's later second thoughts are irrelevant, either to confer standing or, as here, to deny standing. To resolve the issue of standing, we must examine the licensing agreement to determine whether the parties intended to effect a transfer of proprietary rights to the licensee as an incident to protection of its interests. Vaupel, 944 F.2d at 874 (intent of parties controlling).

III.

Ortho does not assert it has standing to sue alone. Moreover, on appeal, Ortho has abandoned paragraph 2.01(a) of the license as a basis for co-plaintiff standing and now relies only upon paragraph 2.01(b) of the license.[6] The burden of

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[6] The Cilag plaintiffs, who are sub-licensees of Ortho only in Europe, do not appeal.

demonstrating standing falls to Ortho, as "[i]t is well established . . . that before a federal court can consider the merits of a legal claim, the person seeking to invoke the jurisdiction of the court must establish the requisite standing to sue." Whitmore v. Arkansas, 495 U.S. 149, 154 (1990); accord Lujan v. Defenders of Wildlife, 112 S.Ct. 2130, 2136 (1992); Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 925, 18 USPQ2d 1677, 1681 (Fed. Cir. 1991). We reach this issue in the context of review of the grant of motions for summary judgment and dismissal for failure to state a claim upon which relief could be granted. We accord each of these determinations plenary review as a matter of law, e.g., Dehne v. United States, 970 F.2d 890, 892 (Fed. Cir. 1992) (dismissal); Intellicall, Inc. v. Phonometrics, 952 F.2d 1384, 1387, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992) (summary judgment), accepting as true all material allegations of Ortho's complaint, which is construed in its favor. Animal Legal Defense Fund, 932 F.2d at 925, 18 USPQ2d at 1682 (quoting Warth v. Seldin, 422 U.S. 490, 501 (1975)); see also 13A Charles Alan Wright, et al., Federal Practice and Procedure § 3531.15 (1984).

A.

Before reaching the issue of standing, Ortho must first demonstrate that the license in fact concerns the '008 patent. In contrast to paragraph 2.01(a), which specifically references "licensed patents," paragraph 2.01(b) expressly grants the right to manufacture EPO and does not address any patents by which it is made. Although the district court concluded that by paragraph 2.01 Ortho received the right to use the inventions claimed in the '008 patent to make EPO (Ortho, 808 F. Supp. at 902, 27 USPQ2d at 1583), it offered no further analysis on how it reached this result. We can only conclude that the court found that a license under the '008

patent could be implied under the law of California, which it found the appropriate jurisdiction under paragraph 10.8 of the licensing agreement. 808 F. Supp. at 902 n.9, 27 USPQ2d at 1583 n.9. See generally 6 Ernest Bainbridge Lipscomb III, Walker on Patents §§ 20:14-20.20 (3d ed. 1987) (describing law of implied patent licenses).

Applying the contract law of California, see Intel Corp. v. International Trade Comm'n, 946 F.2d 821, 826-28, 20 USPQ2d 1161, 1166-68 (Fed. Cir. 1991) (stating principles of California contract law and applying them to interpretation of license agreement for purposes of implied license defense), we agree that paragraph 2.01(b) may reasonably be implied to license Ortho to use the '008 technology. A contrary reading would hardly comport with the requirement under paragraph 2.01(b) that Amgen assist Ortho with its EPO manufacturing efforts.

B.

Despite this implied license, the trial court found Ortho had no proprietary interest in the '008 patent based on its rights under either paragraph (a) or (b). It was a nonexclusive licensee. With respect to patent rights, Ortho had an implied license to use the '008 invention in one location in the United States. It is undisputed that that right was nonexclusive inasmuch as Amgen had the right to license others to do the same. Ortho concedes this point but argues that its additional right to sell EPO abroad as provided in paragraph (b) is an exclusive field of use of the '008 technology which provides standing. We disagree. Ortho commingles its consent from Kirin-Amgen to sell EPO abroad (as expressly stated in paragraph (b) to be necessary) with the rights it received from Amgen under the U.S. patent to use the '008 technology. U.S. patent '008 provides no rights respecting the product EPO per

se. Moreover, a U.S. patent grants rights to exclude others from making, using and selling the patented invention only in the United States. 35 U.S.C. § 154; Vaupel, 944 F.2d at 875. With respect to Ortho's right to sell unpatented EPO abroad, the court correctly held that Ortho's right was not a proprietary right arising from the '008 patent.[7] Indeed, Amgen itself had no right to sell EPO abroad by reason of its obtaining the '008 patent and, thus, could not license that right to Ortho as an incident of patent ownership. With respect to rights under the '008 patent, Ortho had only a nonexclusive right to use the '008 invention at one location in the United States. Thus, considering only this right, Ortho is a bare, that is, nonexclusive, licensee and has no standing to bring or join a suit for infringement against Genetics.

C.

The conclusion that Ortho held only nonexclusive rights under paragraph 2.01(b) would end our inquiry except for the provision in the license agreements which gave Ortho the right to bring appropriate suits if Amgen did not. As provided in paragraph 8.02:

> AMGEN shall have the right, but not the obligation, to bring, defend, and maintain any appropriate suit or action . . . . In the event AMGEN fails to take action with respect to

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[7] Ortho finds fault with the trial court's phraseology that this right "exceeds the scope of the patent" and argues that the court found the agreement unenforceable for this reason. Contrary to Ortho's argument, the court held only that the provision respecting foreign sales of EPO was a contract right, not that the agreement was unenforceable against Amgen.

> such matters within a reasonable period, not more than six (6) months, following receipt of such notice and evidence, ORTHO shall have the right, but not the obligation, to bring, defend, and maintain any appropriate suit or action. Absent an agreement between the parties to jointly bring any action or suit hereunder and share the expenses thereof, any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof.

Other parts of the right to sue clause require that Amgen and Ortho consult and sue together if either "finds it necessary" to "join" the other and that each will "cooperate" with the other.

Ortho argues that the contract should be construed to give each party the right to bring its own action where cooperation is not forthcoming. Amgen argues that the contract provisions, under which Amgen exercised its right to sue alone and keep all damages, would control regardless of whether or not Ortho had an exclusive license. We conclude that the right to sue clause has no effect in this case.

First, a licensee with sufficient proprietary interest in a patent has standing regardless of whether the licensing agreement so provides. Express covenants may, of course, regulate the duties between the licensor and licensee to implement the rights of the parties. Independent Wireless Co., 269 U.S. at 469; Abbott Labs., 1995 WL 50152, at *7. However, a contract cannot change the statutory requirement for suit to be brought by the "patentee." By the same token, a right to sue clause cannot negate the requirement that, for co-plaintiff standing, a licensee must have beneficial ownership of some of the patentee's proprietary rights. A patentee may not give a right to sue to a party who has no proprietary

interest in the patent. Crown Die & Tool Co. v. Nye Tool & Machine Works, 261 U.S. 24, 44 (1923); see also Lifetime Doors, Inc. v. Walled Lake Door Co., 505 F.2d 1165, 1167-68, 185 USPQ 1, 2 (6th Cir. 1974) (bare licensee has no right to be in suit or to appeal; such authorization by patentee has no effect); Overman Cushion Tire Co. v. Goodyear Tire Rubber Co., 59 F.2d 998, 14 USPQ 104 (2d Cir.), cert. denied, 285 U.S. 545 (1932) (nonexclusive licensee has no right to sue or be joined in suit); Philadelphia Brief Case Co., 145 F. Supp. at 429-30, 111 USPQ 180, 183 (contract clause cannot give right to sue where licensee would otherwise have no such right). Here, being only a nonexclusive licensee, Ortho has no inherent or implied right to sue which the clause regulates as between the parties. Thus, we conclude the right to sue clause has no effect on Ortho's standing, one way or the other.

Secondly, under the cited precedent, the requirement that a licensee sue in the name of the patentee is not merely a formality. The patentee is brought into the suit for substantive reasons, namely, to protect its own interests in connection with the charged acts of infringement and "to enable the alleged infringer to respond in one action to all claims of infringement for his act." Independent Wireless Co., 269 U.S. at 468.

A licensee cannot stand by until a patentee's suit is concluded and then seek to vindicate its rights in a second suit. As stated in Birdsell v. Shaliol, 112 U.S. 485, 486-87 (1884):

> [W]hen a suit . . . has been brought and prosecuted, in the name of the patentee alone, with the licensee's consent and concurrence, to final judgment from which, if for too small a sum, an appeal might have been taken in the

> name of the patentee, we should hesitate to say merely because the licensee was not a formal plaintiff in that suit, that a new suit could be brought to recover damages against the same defendant for the same infringement.

While Ortho sought to become part of Amgen's suit at trial, on appeal Ortho seeks approval of an independent second suit in the name of Amgen against the same infringer for the same acts of infringement, namely, Genetics use of the patented '008 technology in the United States, which was the subject of Amgen's suit. Ortho does not claim it was a necessary or indispensable party to Amgen's suit, did not appeal the denials of intervention therein, and did not appeal the order deconsolidating this suit from Amgen's. Moreover, the parties advised the court at the hearing that the Amgen/Genetics litigation has been settled. Thus, Ortho has effectively consented and concurred to suit in the name of the patentee alone.

IV.

CONCLUSION

For the foregoing reasons, the judgment is

AFFIRMED

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ORTHO PHARMACEUTICAL CORP., CILAG GESELLSCHAFT M.B.H., CILAG N.V., CILAG LTD., CILAG S.A.R.L., CILAG G.M.B.H., CILAG S.P.A., CILAG-MEDICAMENTA, LDA., JOHNSON & JOHNSON S.A. (CILAG DIVISION), CILAG AB, CILAG AG, and CILAG AG INTERNATIONAL,	)	
Plaintiffs	)	
v.	)	
GENETICS INSTITUTE, INC. and AMGEN INC.,	)	Civil Action No. 91-12174-Y
Defendants	)	

JUDGMENT

YOUNG, D.J. December 4, 1992

The Court having determined that the Plaintiffs have no standing to sue, judgment shall, and hereby does, enter for the Defendants.

Elizabeth Smith, Deputy Clerk

Approved as to form:

WILLIAM G. YOUNG
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff v. CHUGAI PHARMACEUTICAL CO., LTD and GENETICS INSTITUTE, INC., Defendants	Civil Action No. 87-2617-Y
ORTHO PHARMACEUTICAL CORP., CILAG GESELLSCHAFT M.B.H., CILAG N.V., CILAG LTD., CILAG S.A.R.L., CILAG G.M.B.H., CILAG S.P.A., CILAG-MEDICAMENTA, LDA., JOHNSON & JOHNSON S.A. (CILAG DIVISION), CILAG AB, CILAG AG, AND CILAG AG INTERNATIONAL, Plaintiffs v. GENETICS INSTITUTE, INC. and AMGEN INC., Defendants	Civil Action No. 91-12174-Y

MEMORANDUM AND ORDER

YOUNG, D.J. December 3, 1992

I. INTRODUCTION

A. The Underlying Actions

The motions before the Court stem from two actions which were consolidated by this Court's order on August 27, 1991. The lead case, Civil Action No. 87-2617-Y, is a suit for patent infringement by Amgen, Inc. ("Amgen") against Genetics Institute, Inc. ("Genetics") and Chugai Pharmaceutical Co., Ltd. ("Chugai"). In the lead case, Amgen has already prevailed on the issue of liability. Amgen's U.S. Patent No. 4,703,008 ("the '008 patent") was determined to be valid and Genetics was found to have infringed it. See Amgen. Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989) ("Amgen I"), aff'd in part and rev'd in part, Amgen. Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991) ("Amgen II"), cert. denied, 112 S. Ct. 169 (1991). The issue of damages remains to be litigated.

After the liability determination was made in the lead case, Ortho Pharmaceutical Corp. ("Ortho") and its co plaintiffs filed the member case, Civil Action No. 91-12174-Y, against Genetics and Amgen. Ortho seeks damages for the infringement of the '008 patent.[1]

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[1]The plaintiff Ortho is a wholly owned subsidiary of Johnson & Johnson engaged in the business of research, development, and marketing of pharmaceutical products. The other plaintiffs (the "Cilag co-plaintiffs") are wholly-owned subsidiaries of Johnson & Johnson organized respectively under the laws of various European nations. Defendant Genetics is a Delaware corporation with its principal place of business in Massachusetts. Defendant Amgen is a Delaware corporation with its principal place of business in California.

It should be noted that Ortho and the Cilag co-plaintiffs, after filing the complaint, moved to realign defendant Amgen as a plaintiff, but the Court denied this motion on November 14, 1991.

B. The Motions Before The Court

Genetics now moves either to dismiss Ortho's amended complaint or for summary judgment on the grounds (i) that the amended complaint fails to state a claim upon which relief can be granted because Ortho and the Cilag co-plaintiffs lack standing to bring this action for patent infringement, (ii) that this Court lacks jurisdiction over the subject matter of the amended complaint, and (iii) that prior pending actions instituted elsewhere by Ortho require that the Court dismiss Ortho's amended complaint. Amgen also moves to dismiss Ortho's amended complaint for failure to state a claim on the ground that Ortho lacks standing to bring its action.[2]

Ortho and its co-plaintiffs cross-move pursuant to Federal Rules of Civil Procedure 42 and 56 for leave to intervene in the lead case for the limited purpose of moving for partial summary judgment limiting the damages recoverable by plaintiff Amgen.

II. THE FACTUAL BACKGROUND

A. Amgen's '008 Patent

This dispute centers around U.S. Patent No. 4,703,008 ("the '008 patent"), a patent issued in 1987 to Dr. Fu-Kuen Lin, an Amgen employee, who assigned his rights to the patent to Amgen. The claims in the '008 patent cover certain products of recombinant DNA

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[2]Amgen also contends that Ortho fails to state a claim against Amgen for the simple reason that, while Ortho has named Amgen as a defendant, Ortho in fact seeks no relief from Amgen. Given that this Court has denied Ortho's motion to realign Amgen as a plaintiff, see supra n. 1, Amgen's contention is technically true. The analysis set forth herein, however, moots their point.

technology used to produce Erythropoietin ("EPO"), an important therapeutic agent in the treatment of various blood disorders. More specifically, the '008 patent covers the purified and isolated DNA sequences encoding EPO and the host cells transformed or transfected with a DNA sequence which are used to produce EPO. Amgen II, 927 F.2d at 1203-04. Thus the '008 patent does not cover the product EPO itself, which can also be produced by methods that do not use any recombinant DNA technology. See id.[3]

B. Ortho's License Agreements

In 1984, three years prior to the issuance of the patent, Amgen and Kirin Brewery Company ("Kirin") established a joint venture, Kirin-Amgen, Inc. ("Kirin-Amgen"). At that time, Amgen assigned certain rights to Kirin-Amgen in the then pending application for the '008 patent.

On September 30, 1985, Ortho entered into Technology License Agreements ("TLA's") and Product License Agreements ("PLA's") with Kirin-Amgen and Amgen separately. From Kirin-Amgen, Ortho obtained (1) an "exclusive license"[4] to sell EPO

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[3]For more detailed scientific and historical ground concerning EPO and the claims covered under the '008 patent, see Amgen II, 927 F.2d at 1203-04; Amgen I, 706 F. Supp. at 95-97, 106-11. See generally William R. Carlson, Erythropoietin: The Development of a Pharmaceutical Product (1988) (unpublished A.B. Thesis, Department of Molecular Biology, Princeton University).

[4]The Court notes that both PLA's use the words "exclusive license" to describe the rights Ortho obtains from Kirin-Amgen and Amgen respectively. Whether these words have the legal effect of making Ortho an exclusive licensee under patent law, however, is a question the Court resolves

manufactured using the inventions claimed in the '008 patent throughout the world (except in the U.S., China, and Japan) for all human use except diagnostics, and (2) the right to manufacture EPO, in one location, using the inventions claimed in the '008 patent for sales everywhere outside of the United States (except China and Japan) for all human use except diagnostics. In exchange, Kirin-Amgen received the right to royalties on Ortho's sales abroad. See PLA of Kirin-Amgen and Ortho, Articles 2 and 4, reprinted in Affidavit of Eugene Gelernter ("Gelernter Aff."), Exh. A.

From its license agreements with Amgen, Ortho obtained (1) an "exclusive license" to manufacture EPO using the invention claimed in the '008 patent, in one location, for use or sale in the U.S. for all human use except dialysis and diagnostics, and (2) an "exclusive license" to manufacture EPO using the invention claimed in the '008 patent, in one location in the United States, for use and sale outside the United States (excluding China and Japan). See PLA of Amgen and Ortho § 2.01, reprinted in Gelernter Aff., Exh. B; TLA of Amgen and Ortho § 2.01, reprinted in Affidavit of Ian Crawford ("Crawford Aff."), Exh. F. In return, Amgen would receive royalties on Ortho's resulting sales of EPO in the U.S. Id. at § 4.01.[5]

Both the TLA and the PLA executed by Ortho and Amgen also contain the virtually identical section 8.02 entitled "Infringement by Third Parties." Section 8.02 establishes the rights and obligations of the parties with respect to bringing, defending, and maintaining any appropriate suit or action in the event of a third-party infringement of any licensed patents.

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infra at 10-25.

[5]The Court's reading of the Ortho-Amgen agreements indicates that they did not provide for Amgen to receive any royalties on Ortho's European sales. Neither Amgen nor Genetics has argued to the contrary.

C. The Production and Sale of EPO by Genetics

During the same period, Genetics manufactured EPO in the United States using inventions claimed under its '195 patent issued in June, 1987. Genetics had an agreement with Boehringer Mannheim ("Boehringer"), a German corporation, giving Boehringer the exclusive rights to distribute and sell in Europe EPO manufactured in the U.S. by Genetics under the '195 patent. Under this agreement Genetics made extensive sales of bulk EPO to Boehringer, amounting to $34,100,000.00. Gelernter Aff., Exh. C at 4. In turn, Boehringer made extensive retail sales of this EPO to its customers in Europe.

D. The Resulting Litigation

On October 27, 1987, the date the '008 patent issued, Kirin-Amgen assigned the patent to Amgen. On the same date, Amgen brought suit against Genetics for infringement of the '008 patent. Prior to the trial on the liability issue in the Amgen action, Ortho moved to intervene. Amgen opposed this motion and the Court denied the motion.[6]

The liability phase of the Amgen action was resolved in 1991: Genetics was adjudged to have infringed certain claims of the '008 patent. See Amgen. Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989) ("Amgen I"), aff'd in part and rev'd in part, Amgen. Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991) ("Amgen II"), cert. denied, 112 S. Ct. 169 (U.S. 1991).[7] Thus, the

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[6]Ortho's motion to intervene was not denied for lack of standing. It was denied on the grounds that the motion was untimely and that Amgen could adequately represent Ortho's interests with respect to the liability issue.

issue of liability having been resolved, all that remains to be litigated in this lead case is the issue of damages.

In August, 1991, Ortho and its co-plaintiffs brought an action for damages based on patent infringement against Genetics. Ortho, having obtained from Amgen and Kirin-Amgen the exclusive right to sell in Europe EPO manufactured under the '008 patent, sued to recover damages arising from lost EPO sales in Europe due to Genetics' bulk sale of EPO to Boehringer and Boehringer's retail sales of this EPO throughout Europe. Genetics and Amgen, granted leave to intervene, moved to dismiss Ortho's complaint or for summary judgment. Ortho subsequently amended its complaint to name Amgen as a defendant. As stated above, Genetics and Amgen here move again for dismissal or summary judgment on essentially the same grounds as in their earlier motions. Ortho and its co-plaintiffs cross-move for leave to intervene in the lead case, Amgen's action, for the limited purpose of moving for partial summary judgment to limit the damages recoverable by plaintiff Amgen in that action.

III. THE CENTRAL ISSUES

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[7]These decisions have elicited a variety of scholarly comment. See Dan L. Burk, Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed, 17 Rutgers Computer & Tech. L. J. 1, 66-69 (1991); R. Stephen Crespi, Inventiveness in Biological Chemistry: An International Perspective, U. Pat. [& Trademark] Off. Soc'y 351, 358-65 (1991); Jeffrey P. Kushan, Protein Patents and the Doctrine of Equivalents: Limits on the Expansion of Patent Rights, 6 High Tech. L. J. 109, 110-11, 142 n.126 (1991); Ann S. Viksnins, Comment, Amgen. Inc. v. United States International Trade Commission: Designer Genes Don't Fit, 76 Minn. L. Rev. 161 (1991).

A. The Ortho Action

First, both Genetics and Amgen move for dismissal on the ground that Ortho and its Cilag co-plaintiffs lack standing to bring this infringement action. They contend that, as a general rule of patent law, only the patent owner can bring an infringement action with respect to the patent in issue. They acknowledge that there is a legal exception permitting an "exclusive licensee" to bring such an infringement action if it joins the patent owner, but they argue that neither Ortho nor any of the Cilag co-plaintiffs is an "exclusive licensee" for purposes of this patent infringement action.

Second, they state that, even if Ortho is held to be an exclusive licensee and thus has the "legal capacity" to sue, Ortho does not have "contractual standing" to sue because the terms of § 8.02 of both its TLA and its PLA with Amgen confer on Amgen an exclusive right to sue under the circumstances of this case.

In addition, Genetics contends that this Court lacks subject matter jurisdiction over Ortho's action. More specifically, Genetics claims the Court does not have subject matter jurisdiction because: (i) Ortho's claim of damages arises from the retail sales of the product EPO in Europe, but the '008 patent does not cover EPO, just the gene and host cells used to manufacture EPO; and (ii) the '008 patent's reach does not extend to foreign countries; and (iii) Ortho's damages are predicated on retail sales in Europe by a foreign company (Boehringer) which is not a party to this action.

Finally, Genetics argues that prior pending actions instituted elsewhere by Ortho require that the Court dismiss Ortho's action in this forum. Genetics alleges that Ortho has pending actions in Germany and California seeking the same damages and relief.

B. The Amgen Action

Ortho and its co-plaintiffs seek leave to intervene in Amgen's

lead action for the limited purpose of moving for partial summary judgment to limit the damages Amgen may recover from Genetics. More specifically, Ortho seeks to limit Amgen's recovery to the royalties Amgen itself lost due to infringement by Genetics, thereby precluding Amgen from recovering damages arising from Ortho's lost profits due to loss of sales in Europe. As explained herein, the Court denies the cross-motion for leave to intervene on the ground that the dismissal of Ortho's consolidated action leaves the Court with no basis under Fed. R. Civ. P. 42 for granting Ortho leave to intervene. Thus the Court will not address the merits of Ortho's motion for partial summary judgment as to the damages Amgen may recover in its lead action against Genetics.

IV. ANALYSIS

A. The Ortho Action: The Standing of Ortho and the Cilag Co-Plaintiffs

"The right to sue under the patent laws on a patent, as distinguished from the right to sue for a breach of contract concerning a patent, naturally depends upon those laws." Philadelphia Brief Case Co. v. Specialty Leather Prods. Co., 145 F. Supp. 425, 427 (D.N.J. 1956) aff'd 242 F.2d 511 (3rd Cir. 1957). 35 U.S.C. § 154 (1988) provides in pertinent part that:

> Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, or selling the invention throughout the United States, and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process[.]

Thus, "a patent provides its owner with the right to exclude others from making, using, and selling the claimed invention."

Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 875 (Fed. Cir. 1991). Under United States patent law, one seeking to recover money damages for the infringement of a U.S. patent must have held legal title to the patent at the time of infringement. Arachnid, Inc. v. Merit Indus., Inc., 19 U.S.P.Q.2d (BNA) 1513, 1517 (Fed. Cir. 1991); see also III. P. Rosenberg, Patent Law Fundamentals § 17.09 [l][b] at 17-151 (2d ed. 1975). It is undisputed that Amgen, not Ortho, held legal title to the '008 patent at the time of infringement by Genetics.

There is, however, an exception to this general rule. "An exclusive licensee generally has standing to sue for infringement against anyone operating without the stated authority in the stated area of exclusivity." 6 D. Chisum, Patents § 21.03[2][c] at 21-157 (1991); see also Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459, 467-68 (1926); Kalman v. Berlyn Corp., 914 F.2d 1473, 1481-2 (Fed.Cir. 1990); Western Electric Co. v. Pacent Reproducer Corp., 42 F.2d 116, 119 (2d Cir. 1930), cert. denied, 282 U.S. 873 (1930); Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc., 222 U.S.P.Q. (BNA) 143, 149 (D. Kan. 1983); Philadelphia Brief Case Co. v. Specialty Leather Prods. Co., 145 F. Supp. 425, 428 (D.N.J. 1956) aff'd 242 F.2d 511 (3rd Cir. 1957). Under this exception, the exclusive licensee "has the power to join the patent holder in a suit for infringement either as a willing or unwilling plaintiff or defendant, in order to enforce the right granted in the license." Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc., 222 U.S.P.Q. (BNA) at 149 (citing Independent Wireless, 269 U.S. 459); see also Kalman, 914 F.2d at 1481-82); 6 Chisum, Patents § 21.03[2][c] at 21-157. It is well settled, however, that a mere non-exclusive licensee has no standing to sue for infringement. Kalman, 914 F.2d at 1481 (citing Waterman v. Mackenzie, 138 U.S. 252, 255 [1891]).

Therefore, the Court must determine whether Ortho or any of the Cilag co-plaintiffs is an exclusive licensee. "In its simplest form, a license means only leave to do a thing which the licensor would otherwise have a right to prevent. Such a license grants to the licensee merely a privilege that protects him from a claim of infringement by the owner of the patent monopoly." Western Electric Co., 42 F.2d at 118. An "exclusive license," however, provides the licensee with the legal grounds to prevent the patent owner from granting further licenses for the manufacture, use, and sale of the inventions claimed under the patent, either directly or by condoning infringing activity. See id. at 118, 119; see also 6 Chisum, Patents § 21.03[2][c] at 21-157 to 21-158.

A licensee can be deemed exclusive where the license pertains to less than all three of the rights granted under the patent, such as where the licensee has obtained only the exclusive right to sell the patented invention, see Weinar v. Rollform Inc., 744 F.2d 797 (Fed. Cir. 1984), cert. denied, 470 U.S. 1084 (1985). Furthermore, an exclusive license can be created by a grant of exclusivity based solely on geographic, time, or field-of-use limitations. 6 Chisum, Patents § 21.03[2][c] at 21-159; see. e.g., Independent Wireless, 269 U.S. 459 (exclusive licensee's field-of-use grant was limited to use of the patented invention for commercial radio purposes); Pratt & Whitney Co. v. United States, 153 F. Supp. 409 (Ct. Cl. 1957) (exclusive licensee's field-of-use grant for the patented device was limited to use with engines in aircraft and guided missiles). Finally, it should be stressed that the test for exclusivity is not whether the license is exclusive as against the licensor, but rather whether the licensor has promised explicitly or implicitly not to grant any additional licenses to third parties. 6 Chisum, Patents § 21.03[2][c] at 21-158; see, e.g., Western Electric Co., 42 F.2d at 120 ("[A] license ... which reserves to the licensor, and to possible prior licensees, the privilege of practicing the invention, but contains an

implied promise that the licensor will give no further license within the specified field of use, entitles the promisees to join with the licensor in an infringement suit."); Research Frontiers Inc. v. Marks Polarized Corp., 290 F. Supp. 725, 727 (E.D.N.Y. 1968); Wing Engineering Corp. v. United States, 151 F. Supp. 314, 315 (Ct. Cl. 1957) (holding that where Wing was given the exclusive right to make, use, and vend the patented article, subject only to reservation that patent holder could do so as well, Wing was an exclusive licensee for standing purposes); Philadelphia Brief Case Co., 145 F. Supp. at 428.

In essence, the theory behind permitting the exclusive licensee to sue for patent infringement is that such a licensee "comes so close to having a truly proprietary interest in the patent" that she should be entitled to sue. Philadelphia Brief Case Co., 145 F. Supp. at 428; see also 6 Chisum, Patents § 21.03[2][c] at 21-157 to 21-158. To determine whether Ortho has such a proprietary interest, the Court must examine the legal effect of the substantive provisions of the license agreements. It is not dispositive that these agreements characterize Ortho's license as "an exclusive license." Cf. Vaupel, 944 F.2d at 875 ("whether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name which it calls itself, but upon the legal effect of its provisions") (quoting Waterman v. Mackenzie, 138 U.S. 252, 256 [1891]); American Type Founders, Inc. v. Dexter Folder Co., 53 F. Supp. 602, 60 (S.D.N.Y. 1943) ("Although the agreement is referred to as an 'exclusive license,' this is not conclusive as to its legal effect."). Thus, if the terms of the Ortho-Amgen Technology License Agreement and of their Product License Agreement preclude Amgen from granting further licenses under the patent within the stated area given to Ortho, then Ortho is an "exclusive licensee" with the legal capacity to sue for patent infringement within this stated area.

It should be stressed, however, that it is not enough that the Ortho-Amgen agreements grant Ortho certain exclusive rights. It is also necessary that the infringement have occurred within Ortho's "stated area of exclusivity." 6 Chisum, Patents § 21.03[2][c] at 21-157. In other words, to be an exclusive licensee for purposes of this infringement action against Genetics, Genetics' adjudicated act of infringement must have infringed on one of Ortho's exclusive rights:

> It seems clear . . . that the owner of a patent who grants to another the exclusive right to make, use, or vend the invention,...must allow the use of his name as plaintiff in any action brought at the instance of the licensee in law or in equity to obtain damages for the injury to his exclusive right by an infringer[.]

Independent Wireless, 269 U.S. at 468 (emphasis added). Therefore, before the Court examines the terms of the Amgen-Ortho agreements, the Court must clarify the nature of the patent infringement which Genetics has been adjudged to have committed.

The '008 patent covers the DNA sequences and transfected host cells used to manufacture EPO. In essence the patent covers certain products - machines or starting materials - used to manufacture EPO, but does not cover the product EPO itself.[8] Genetics infringed the '008 patent by using the DNA sequences and transfected host cells covered

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[8]The Court emphasizes that the claims covered by the '008 patent are product claims, not process claims. See Amgen I, 706 F. Supp. at 110.

by the patent to manufacture EPO in the United States.

While Ortho's arguments are not entirely clear, Ortho appears to be making two different arguments as to how this infringing act injured its exclusive rights thereby giving Ortho standing as an exclusive licensee to sue Genetics for patent infringement. These two arguments define differently the exclusive right which has been infringed. The Court will examine each of these in turn.

First, Ortho contends that the license agreements give it the exclusive right to use the patented inventions in the United States to make EPO. Ortho admits that in these agreements Amgen reserves the right to use the patented inventions in the U.S. to make EPO for sale in the U.S. for diagnostic and dialysis purposes. Ortho correctly argues, however, that the exclusivity of its license to use the inventions claimed under the '008 patent in the U.S. to make EPO depends not on whether Amgen reserved the same right for itself, but rather on whether Amgen expressly or impliedly promised not to grant this right to other third parties. See discussion, supra at 12.

The Court therefore must determine whether the Ortho-Amgen agreements contain an explicit or implicit promise by Amgen not to grant any further licenses to third parties to manufacture EPO in the U.S. using the inventions claimed under the '008 patent.[9] Ortho insists that it does

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[9]In determining the legal effect of the license agreements, the Court is required to interpret the terms of these agreements. None of the parties has briefed the question of which law the Court should apply in interpreting such contracts. That is, do federal courts, sitting in federal question jurisdiction patent cases rely on state contract law or do they

contain such a promise. Ortho's Second Opposition Memorandum at 4. Genetics contends that it does not. Genetics' Reply Memorandum in Support of Motion to Dismiss and for Summary Judgment ("Genetics Reply Memorandum") at 3. Amgen never expressly contends that it retained this right to grant further licenses under its agreements with Ortho. Amgen's Reply to Ortho's Second Opposition Memorandum ("Amgen Reply Memorandum") at 4.

Ortho relies on section 2.01 of the Amgen-Ortho PLA. This provision grants Ortho "an exclusive license" to use the inventions claimed in the '008 patent for the manufacture of EPO in one location in the U.S. for (1) use or sale in the U.S. for all human use except dialysis and diagnostics, and (2) for use and sale outside the U.S. (excluding China and Japan). Implicitly, Amgen retains for itself the right to manufacture EPO in the U.S. under the '008 patent for use or sale in the

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apply some sort of federal common law of contracts? The few cases cited by the parties to support their particular interpretations of the disputed provisions in the license agreements do not reflect any consistent view or theory as to which law applies.

According to 6 Lipscomb, Walker on Patents § 20:58 at 202 (1987), "[t]he general rules of construction for contracts are applicable to the construction of patent licenses. The construction of patent license agreements is governed by state law." The Court adopts this view, and therefore applies California contract law because the license agreements specify that they are to "be construed in accordance with the internal laws, and not the law of conflicts, of the state of California applicable to agreements made and to be performed in that state." PLA § 10. 8 .

U.S. for dialysis and diagnostics. Ortho admits this. Ortho Second Opposition at 4. Equally clearly, this provision precludes Amgen from licensing to any third parties the right to manufacture EPO in the U.S. under the '008 patent for sale abroad. This provision, however, does not expressly state whether Amgen also retains the right to grant additional licenses to use the patented '008 inventions in the U.S. to make EPO for use or sale in the U.S. for dialysis and diagnostic purposes.

The Court interprets § 2.01 as creating no such implied promise by Amgen not to sub-license its right to manufacture EPO in the U.S. using the inventions claimed under the '008 patent. The Court should "not read limitations into the [license] agreement which could have been readily inserted by the parties[.]" 6 Lipscomb, Walker on Patents § 20:58 at 203 (1987). It is true that § 2.01 refers to Ortho's license as an "exclusive license". The Court interprets this reference to an "exclusive license" to mean only that Amgen cannot license to a third party Ortho's exclusive right to manufacture EPO in the U.S. for sale abroad and not that Amgen can not sub-license its own right to manufacture EPO in the U.S. for sale in the U.S. for diagnostics or dialysis.

The essence of Ortho's second argument is that section 2.01(b) of the PLA grants Ortho an exclusive field-of-use license and that Genetics' infringing act intruded upon this exclusive field-of-use. More specifically, Ortho argues it has the exclusive license to use the '008 patented inventions in the United States to make EPO for the purpose of sale abroad. Ortho's Second Opposition Memorandum at 2. Thus, Ortho states, Genetics infringed this exclusive right by using the claimed inventions in the U.S. to make EPO to be sold to Boehringer for resale in Europe. Therefore, Ortho concludes, it has standing as an exclusive licensee to sue Genetics for damages arising from this infringement.

In response, Genetics and Amgen essentially argue that Ortho confuses its exclusive right under the license agreement with its exclusive right under the patent. Because the territorial effect of the '008 patent, like any U.S. patent, is limited to the U.S., see 35 U.S.C.§ 154; III P. Rosenberg, Patent Law Fundamentals § 18.01 (2d ed. 1975), and because the '008 patent covers only certain products used to make EPO, and not EPO itself, see supra pages 3-4, they argue Ortho has no such exclusive field-of-use right under the '008 patent to use the claimed inventions in the U.S. to make EPO for sale abroad. Thus Amgen and Genetics contend that Ortho may have such an exclusive right under contract law as against Amgen, but not under patent law as against a third-party infringer. In short, they claim that the exclusive right Ortho asserts is only contractual because (1) it exceeds the territorial boundaries of a United States patent, and (2) it is predicated on a field-of use limitation which relates not to the use, sale, or making of the '008 patented inventions, but to the sale of the resulting unpatented EPO.

While Amgen and Genetics fail to offer any case law to support their view, their argument is persuasive at least with respect to their second point.[13] The case law makes clear that the standing of an exclusive licensee can be predicated on the grant of an exclusive right to make, use, or

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[13]The Court, however, disagrees with Amgen's and Genetics' first point contending that Ortho's asserted exclusive license exceeds the territorial limitations of the '008 patent. Were this Court to hold that the field-of-use limitation in the license was within the scope of the '008 patent, the Court would then hold that it does not exceed the territorial boundaries of the patent because it simply licenses the use of the patented invention in the United States for a particular purpose.

sell a patented invention within a limited field. See discussion supra pages 11-12. If the field-of-use limitation in the license exceeds the scope of the patent, however, such a license may be enforceable under contract law, but is not enforceable under patent law. The parties do not cite, and this Court has not found, any case in which a court, in dealing with whether a licensee has standing as an exclusive licensee to sue a third party for patent infringement, has been faced with the issue of whether the field-of-use restrictions in the subject license exceed the scope of the patent. There is, however, significant case law in which the Supreme Court, as part of determining whether certain patent licenses violate antitrust law, has been faced with the issue of whether the field-of-use restrictions in licenses such as these exceeds the scope of the patent. The Supreme Court has had to evaluate whether the license granted by the patent owner contains a field-of-use limitation which goes beyond the scope of the patent since such a license is not shielded by patent law from the application of the antitrust laws. See Ethyl Gasoline Corp. v. United States, 309 U.S. 436 (1940). Thus, in Ethyl Gasoline Corp., the Court states:

> The patent law confers on the patentee a limited monopoly, the right or power to exclude all others from manufacturing, using, or selling his invention. The extent of that right is limited by the definition of his invention, as its boundaries are marked by the specifications and claims of the patent. He may grant licenses to make, use or vend, restricted in point of space or time, or with any other restriction upon the exercise of the granted privilege, save only that by attaching a condition to his license he may not enlarge his monopoly and acquire some other which the statute and the patent did not give.

309 U.S. at 456 (citations omitted) (emphasis added). Similarly, in United States v. General Electric Co., 272 U.S. 476, 489 (1926), the Court states that "the patentee may grant a license to make, use, and vend articles under the specifications of his patent for any royalty or upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure."

While this Court is not faced with the question of whether the patent license in issue violates antitrust law, it too must determine whether the field-of-use restriction in the license Amgen granted to Ortho exceeds the scope of the '008 patent. The starting point for this determination is the claims covered by the '008 patent. The '008 patent covers product claims, not process claims. More specifically it covers specific products - certain DNA sequences and transfected host cells - which can be analogized to "machines" or "starting materials" used for manufacturing EPO. It does not cover the process of manufacturing recombinant EPO. Amgen I, 706 F. Supp. at 106-08. Nor does it cover the product EPO itself which is made through use of these machines. As this Court explained in Amgen I, "[a] product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured. A process patentee's power extends only to those products made by the patented process." Id. at 107 (quoting United States v. Studiegesellschaft Kohle, 670 F.2d 1122, 1127-28 [D.C.Cir. 1981]) (emphasis added).

The field-of-use limitation on Ortho's asserted exclusive license restricts Ortho's use of the patented DNA sequences and host cells to the making of EPO for sale abroad. If we analogize the DNA sequences and host cells to a machine, Ortho's asserted exclusive license then can be seen as a license to use a patented machine to make a certain

unpatented product for sale abroad. Such a restriction on the sale of the unpatented product exceeds the scope of the patent on the machine. See Robintech, Inc. v. Chemidus Wavin, Ltd., 450 F. Supp. 817 (D.D.C. 1978). In Robintech, a patentee had granted a license for the restricted use of a patented apparatus to produce unpatented pipes and pipe fittings for export to certain countries outside the United States. The court held that patent law did not provide a basis for a patentee to use its patent on an apparatus to control the distribution of unpatented products made with the apparatus. Id. at 820-21. In granting a license with such a limitation, the court concluded, the patentee had "arrogated power beyond the scope of his monopoly under law." Id. at 822.

On this basis, this Court holds that a field-of-use license which grants an exclusive license to use the inventions claimed under the '008 patent (the DNA sequences and transfected host cells) in the U.S. to make an unpatented product (EPO) for sale abroad exceeds the scope of the '008 patent. Thus, the exclusive license Ortho asserts, that is to use the patented products to manufacture EPO in the U.S. for export, is merely exclusive under contract law as against Amgen, but is not exclusive under patent law as against third party infringers. Hence, as matter of law, Ortho lacks standing as an exclusive licensee to sue Genetics for infringing the '008 patent.[14] Having determined that Ortho is not an

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[14]Ortho also argues that as a matter of equity and policy it should have standing to sue here because it is the only party which can recover from Genetics those damages resulting from lost European sales. As it also argues in its motion to intervene in the lead case, Ortho contends that Amgen is not entitled to recover damages for lost European sales because Amgen, under the license agreements, is not entitled to any royalty payments from Ortho on such sales.

exclusive licensee, the Court must also conclude that the Cilag

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Whatever the merits of this argument may be, it cannot provide the basis for standing. The key question for determining standing of a licensee is whether the licensee as matter of law has an exclusive property interest in the patent itself, not whether the licensee in fact has been harmed by a third-party infringer. As Judge Learned Hand explained in A.L. Smith Iron Co. v. Dickson, 141 F.2d 3, 6 (2d Cir. 1944), there are strong policy reasons why patent law does not confer standing on a nonexclusive licensee to sue a third party for infringement even though the licensee has suffered due to the infringement:

> It is indeed true that a mere licensee may have an interest at stake in such a suit; his license may be worth much more to him than the royalties which he has agreed to pay, and its value will ordinarily depend on his ability to suppress the competition of his rivals. The reason why he is not permitted to sue is not because he has nothing to protect. But against that interest is the interest of the infringer to be immune from a second suit by the owner of the patent; and also the interest of the patent owner to be free to choose his forum . . . . Indeed, the owner may have granted a number of licenses, and it would be exceedingly oppressive to subject him to the will of all his licensees. These two interests in combination have been held to over-weigh any interest of the licensee[.]

co-plaintiffs are not exclusive licensees because, as sub-licensees of Ortho, their rights are derivative of Ortho's.[15]

For the foregoing reasons, the motions for dismissal and for summary judgment by Amgen are ALLOWED.[16]

B. The Amgen Action: Ortho's Cross-Motion to Limit the

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[15]The Court notes that the co-plaintiffs would not have standing to sue as exclusive licensees even if Ortho were determined to have such legal capacity. This is because the sub-licenses the co-plaintiffs received from Ortho do not involve any right of manufacture of EPO under the '008 patent in the U.S. These sub-licenses only grant each Cilag affiliate the exclusive right to sell EPO in a particular country abroad. Thus, Genetics' act of infringement - the use of the patented inventions to manufacture EPO in the United States - did not infringe on the exclusive rights of these affiliates. Therefore they lack the legal capacity to sue Genetics even if Ortho does not.

[16]Having determined as matter of law that Ortho and its co-plaintiffs are not exclusive licensees for the purpose of suing Genetics for infringement of the '0008 patent, the Court need not address the issues raised by the parties concerning the allocation of the right to sue under section 8.02 of the PLA. A contractual provision providing a licensee with a right to sue cannot confer on that licensee a right to sue under the patent laws where there is no such right under the patent laws. See 6 Chisum, Patents § 21.03[2][e] at 21-161 (citing inter alia Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24 [1923]; Agra-shell, Inc. v. Hammons Prod. Co., 352 F.2d 443, 446 [8th Cir. 19656]; Philadelphia Brief Case Co., 145 F. Supp. at 130).

Damages Amgen May Recover

Ortho and its co-plaintiffs have also filed a cross-motion for leave to intervene in the lead case for the limited purpose of moving for partial summary judgment limiting the damages recoverable by plaintiff Amgen in that action. Their pleading states that they bring this cross-motion pursuant to Rules 42 and 56 of the Federal Rules of Civil Procedure. Ortho's Cross-Motion for Leave to Intervene at 2. Neither of these rules, however, provides a basis for here permitting Ortho's intervention in the lead case now that Ortho's own action has been dismissed for lack of standing. Rule 42(a) explains the circumstances wherein a federal court may consolidate actions pending before it.[17] This rule might

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[17]Rule 42 provides:

> (a) Consolidation. When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.
>
> (b) Separate Trials. The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right

permit the intervention Ortho seeks if Ortho's action were still alive. Given, however, that this Court has dismissed Ortho's action, the Court no longer has two consolidated cases before it. Therefore, Rule 42 cannot provide a basis for granting Ortho's cross-motion to intervene. Nor do Rule 42(b) or Rule 56 provide a basis for allowing Ortho to intervene. Rule 42(b) governs when a federal court may hold a separate trial on one or more of the claims in a case. Rule 56 governs motions for summary judgment. Thus, without addressing the substantive merits of Ortho's motion for partial summary judgment, this Court DENIES Ortho's cross-motion for leave to intervene.[18]

> of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

[18]I conclude, based on the information before the Court, that Ortho's motion for intervention should be denied even if treated as a motion brought pursuant to Fed. R. Civ. P. 24. Rule 24, entitled "Intervention," sets forth the requirements for "intervention of right" and "permissive intervention." Rule 24(a), governing intervention of right, requires a court to grant intervention where:

> Upon timely application anyone shall be permitted to intervene in an action: (1) when a statute of the United States confers an unconditional right to intervene; or (2) when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing

parties.

Rule 24(b), governing permissive intervention, explains when a court may, but is not required to, permit intervention:

> Upon timely application anyone may be permitted to intervene in an action: (1) when a statute of the United States confers a conditional right to intervene; or (2) when an applicant's claim or defense and the main action have a question of law or fact in common. . . . In exercising its discretion the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties.

Rule 24(a) Analysis: There is no federal statute conferring on Ortho an unconditional right to intervene in the case at bar. Therefore, Ortho only can intervene of right if it meets four requirements:

> (1) its application must be "timely";
>
> (2) it must claim an interest relating to the property or transaction which is the subject of the action;
>
> (3) it must be so situated that the disposition of the action may as a practical matter impair or impede [its] ability to protect that interest; and
>
> (4) it must show that its interest will not be adequately represented by Amgen and/or Genetics.

Travelers Indem. Co. v. Dingwell, 884 F.2d 629, 637 (lst Cir.

1989).

The four-factor approach to evaluating timeliness is set forth in Banco Popular de Puerto Rico v. Greenblatt, 964 F.2d 1227 (lst Cir. 1992). Ortho would appear to have no difficulty meeting the inadequacy of representation requirement by virtue of the fact that Genetics and Amgen appear close to settlement. See Conservation Law Foundation, 966 F.2d at 44. While it may have more difficulty meeting the timeliness requirement, Ortho most clearly does not satisfy the second requirement -- the interest requirement. The First Circuit's approach to determining whether an applicant's claimed interest justifies intervention of right is set forth in Conservation Law Foundation. Inc. v. Mosbacher, 966 F.2d 39 (lst Cir. 1992). The First Circuit follows neither the liberal approach of the D.C. Circuit and three other circuits, nor the more restrictive approach of the Courts of Appeals for the Fifth, Seventh, Eleventh, and Federal Circuits. Id. at 41-43. Instead, the First Circuit requires inter alia that "the interest must be direct, not contingent." Id. at 42 (quoting Travelers Indem., 884 F.2d at 638). While Ortho may have an interest in preserving Genetics' assets so that, if Ortho obtains a judgment in another pending action in which Genetics is a defendant, see supra at 8, Ortho will be able to recover damages, this is only a contingent interest because it depends on the contingency of Ortho's success in some other suit. See generally id. at 42 (discussing ruling in Travelers Indem., 884 F.2d at 638-39 that the applicant's interest was only contingent and therefore did not merit intervention of right). Because Ortho does not appear to satisfy the interest requirement, intervention must be denied under Rule 24(a).

Rule 24(b) Analysis: Likewise, Ortho cannot satisfy the requirements for permissive intervention. As a threshold

SO ORDERED.

William G. Young
United States District Judge

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matter, an applicant for intervention under Rule 24(b) must establish an independent basis for jurisdiction. International Paper Co. v. Jay, 887 F.2d 338, 346 (lst Cir. 1989). This Court has ruled that Ortho lacks the legal standing to state a claim against Genetics under the patent law. Ortho appears to have no other claim against Genetics that could confer federal jurisdiction. Therefore, without even considering whether Ortho meets the other requirements of Rule 24(b), this Court must deny Ortho's application for permissive intervention.

C-1

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

AMGEN, INC.,

Plaintiff,

CIVIL ACTION NO. 87-2617-Y

v.

CHUGAI PHARMACEUTICAL CO., LTD., et al.,

Defendants.

REPORT AND RECOMMENDATION RE: MOTION OF ORTHO PHARMACEUTICAL CORPORATION TO INTERVENE IN THIS ACTION PURSUANT TO RULES 24(a)(2) and 24(b)(2), FED. R. CIV. P. (DOCKET 116)

MAY 5, 1989

SARIS, U.S.M.

On March 17, 1989 Ortho Pharmaceutical Corporation ("Ortho") moved to intervene in this action pursuant to Fed. R. Civ. P. 24(a)(2) and 24(b)(2). Plaintiff Amgen, Inc., ("Amgen") vigorously opposes the motion. The court recommends that the motion be denied on the ground it is untimely.

Background

The instant action was filed on October 27, 1987. Amgen alleges that defendants Chugai Pharmaceutical Co. ("Chugai") and Genetics Institute, Inc. ("GI") have infringed its patent No. 4,703,008 ("'008 patent") which includes claims

for DNA sequences encoding erythropoietin as well as host cells transformed or transfected with a DNA sequence. Erythropoietin is a protein which stimulates the body's production of red blood cells and is used primarily for the clinical treatment of anemia, particularly anemia caused by renal disease. Chugai and GI have filed a counterclaim charging Amgen with, among other things, infringing their patent No. 4,677,195 ("'195 patent"), a patent for compositions comprised of highly purified erythropoietin. GI is the owner of the patent and Chugai is the exclusive licensee.

The day after Amgen brought this suit in Boston, GI and Chugai filed suit against Amgen and Kirin-Amgen, Inc., a joint venture company of Amgen and the Japanese company, Kirin Brewery, in the Southern District of California. Defendants counterclaimed for infringement of the '008 patent. This Los Angeles suit is the mirror image of the Boston suit so far as the patent issues are concerned.

In February, 1988, in the California action, GI and Chugai moved to join Ortho as an additional party defendant pursuant to Fed. R. Civ. P. 15 and 20 on the ground that Ortho had entered into product and technology licensing agreements were both Amgen and Kirin-Amgen; that the licensing agreements provided for the sharing of technology and resources for the commercialization of the allegedly infringing erythropoietin; that their right to relief arose out of the same transactions or occurrences as against Amgen; and that there were common factual and legal issues in the case, in particular the issue of infringement of the patent, and inducement of infringement. See Docket 117, Appendix, Ex. C. Ortho moved to dismiss for lack of venue pursuant to 28 U.S.C. § 1400(b). Venue was reserved as a trial issue by decision of February 6, 1989, and Ortho's Answer was filed on February 27, 1989. The Answer asserts infringement of the '008 patent and invalidity of the '195 patent.

Meanwhile, the Massachusetts action was not dormant. Chugai and GI filed a motion for partial summary judgment on the claim that Amgen infringed the claims of the '195 patent. On February 24, 1988, the court heard oral argument and then granted the motion. Chugai filed a motion for summary judgment on May 12, 1988 seeking a determination that the '008 patent is unenforceable due to Amgen's alleged acts of patent misuse or, in the alternative, that the '008 patent contains no process claims, and thus does not cover Chugai's process of manufacturing recombinant erythropoietin. The court granted Chugai's motion for partial summary judgment only to the extent of ruling that the '008 patent does not contain a process claim. See Memorandum and Order, dated January 31, 1989.

On January 24, 1989 the Court issued a temporary restraining order enjoining defendants from, among other things, exporting, shipping or delivering to others certain recombinant erythropoietin. On February 2, 1989, the court heard oral argument on plaintiff's motion for a preliminary injunction. At the outset the trial judge noted that the case "cries out for a trial", that he was trying a criminal case which would last a year, and suggested consent to trial before a magistrate in "view of the necessity, really, the litigation necessity, to try this case and move it forward." Transcript of hearing, dated February 2, 1989.

On February 7, 1989, the court issued an order finding that Amgen had shown a reasonable likelihood of success on the merits of the validity of the patent; that it would suffer irreparable injury due to the needs of an incipient market and attendant burdens on a new company; that the balance of equities was best struck by mandating an injunction that required the defendant GI to place with the Court all profits of the sale of erythropoietin ("EPO"); and that as to the public interest, "recombinant EPO is an extraordinarily valuable

medicine that promises marked relief from renal failure." Because of this public interest, the court would not enter an order to delay or prevent production or shipping of erythropoietin.

The case was referred to a magistrate on February 7, 1989. Discovery has been expedited, and trial is scheduled to begin on August 7, 1989. According to counsel, depositions have been taking place as many as six days a week, often with more than one deposition occurring in a day. The parties have agreed that the case should be bifurcated into the liability and damage issues.

On March 17, 1989 Orth moved to intervene. Oral argument on the motion to intervene took place on April 27, 1989. At the hearing counsel for Amgen, Chugai and GI all concurred that the trial should go forward as scheduled, and opposed any continuances.[1]

ARGUMENT

The threshold question is whether a magistrate has the authority under 28 U.S.C. § 636(c) to rule on a motion to intervene pursuant to Fed. R. Civ. P. 24. Section 636(c)(1) states:

> Upon the consent of the parties, a full-time United States magistrate...may conduct any or

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[1]Originally, in their joint response to the motion to intervene, defendants conditionally consented to the motion for intervention as long as they got an extension of at least one month to review the documents in Ortho's possession. Docket 129. At the hearing, defendants changed their position, and urged that the trial go forward as scheduled.

> all proceedings in a jury or nonjury civil matter and order the entry of judgment in the case, when specifically designated to exercise such jurisdiction by the district court or courts he serves.

(Emphasis added). See Fed. R. Cvi. P. 73 (no district judge or magistrate shall be informed of a party's response to the clerk's notification concerning the opportunity to consent to the exercise by a magistrate of civil jurisdiction "unless all parties have consented have consented to the referral of the matter to a magistrate).

The requirement of consent is of constitutional dimension. The First Circuit has held that the delegation of power of magistrates to conduct consensual trials and enter judgments without de novo review by a district judge does not violate the litigants' Article III rights where the parties have voluntarily consented to have the action handled through to judgment by a magistrate. See Goldstein v. Kelleher, 728 F.2d 32, 36 (1st Cir. 1984) cert. denied, 469 U.S. 852 (1984) (litigants' Article III interests are safeguarded by the consensual nature of the reference).

Neither the statute nor the Federal Rules of Civil Procedure address the authority of a magistrate to rule on a motion to intervene pursuant to Fed. R. Civ. P. 24(a) and (b) after the original parties have consented to trial before the magistrate. As Wright and Miller commented:

> It seems possible that in some cases, after the original parties have consented that a magistrate should exercise the district court's jurisdiction, an additional party or parties may enter the case and insist on a trial before an Article III judge. The Act and Rule 73(a)

> make no provision for subsequently added parties, but the legislative history indicates that the voluntary consent of all the parties is required to invoke the jurisdictional provisions of Section 636(c).

Wright and Miller, 12 Federal Practice and Procedure § 3077.2 (1988 Supp. p. 61).

Under Rule 24(a), upon timely application, one has an absolute right to intervene when the applicant claims an interest in the property or transaction involved which is not adequately protected by the existing parties, and which might be adversely affected by the outcome of the action. 3B Moore's Federal Practice ¶ 24.05 (1987 at p. 24-26).

Here, none of the parties has challenged the authority of the magistrate to rule on the motion to intervene, and indeed at a status conference, counsel for Ortho indicated that Ortho would probably consent to trial before the magistrate. Nonetheless, as a matter of constitutional law, statutory construction, and interpretation of Fed. R. Civ. P. 73, this court concludes that it does not have the authority pursuant to 28 U.S.C. § 636(c) to rule on the motion to intervene. See Guess v. Chenault, 108 F.R.D. 446, 449 (N.D. Ind. 1985) (when plaintiff filed an amended complaint adding another defendant as a "real party in interest" after all the parities had consented to trial before a magistrate, the magistrate did not have jurisdiction over this new defendant which did not consent to trial before him, but he did have authority to retain jurisdiction over the original parties, and to sever the claim against the non-consenting defendant pursuant to Fed. R. Civ. P. 42(b)). Accordingly, this court will issue a report and recommendation to the trial court with respect to the motion to intervene.

2. Intervention.

Ortho argues that as a licensee of the patent it should be permitted to intervene as of right pursuant to Fed. R. Civ. P. 24(a)(2) and (b)(2). In support of the motion, it submits the affidavit of Dennis N. Longstreet, the President of the Biotech Division. See Appendix, Ex. A. The affidavit contains the following relevant information. Ortho, a wholly owned subsidiary of Johnson & Johnson, is involved in the research, development and marketing of pharmaceutical and biological productions. It has been interested in the potential for erythropoietin since at least the early 1980's when it participated in an experiment purifying small quantifies of erythropoietin under zero gravity conditions on a Space Shuttle mission.

In the mid-1980's Amgen had done significant bio-engineering work on erythropoietin, but had financial and staffing concerns. In September 1985 Amgen and Ortho entered into a series of contracts pursuant to which Ortho provided Amgen with millions of dollars of financial support and with technical expertise to complete the erythropoietin project. In exchange, Amgen granted Ortho certain of its patent rights. Specifically, Ortho received the exclusive license to offer erythropoietin in the United States except for dialysis and diagnostic applications which were reserved to Amgen. Ortho was granted foreign exclusivity for erythropoietin sales including dialysis.

Ortho contends that Amgen failed to live up to its obligations under the Exclusive Product License to represent its interests before the Food and Drug Administration. This alleged breach of duty has resulted in litigation and an arbitration proceeding. Both Amgen and Ortho, at the hearing, agreed that relations between the two companies are acrimonious.

The proposed complaint of intervenor Ortho charges GI and Chugai with violating the '008 patent, and seeks a declaratory judgment that defendants' patent '195 is valid.

Fed. R. Civ. P. 24(a) provides:

> Upon timely application anyone shall be permitted to intervene in an action...when the applicant claims an interest relating to the property or transactions which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

Rule 24(b)(2) provides that on timely application, anyone may be permitted to intervene in an action when a applicant's claim or defense and the main action have a question of law or fact in common.

Ortho has demonstrated -- and there appears to be no dispute -- that it has an interest relating to the property or transaction which is the subject of the action, and that it is so situated that the disposition of the action would as a practical matter impair or impede its ability to protect that interest. Certainly Ortho's claims and defenses and the main action present questions of law and fact in common. Indeed, courts have granted motions to intervene brought by exclusive licensees of a patent in litigation involving the validity or infringement of the patent. See Fisher v. The Gillette Co., 505 F. Supp. 184, 186 (N.D. Ill. 1981) (it is highly desirable that in a litigation between the patentee and a major alleged infringer,

the exclusive licensee with a substantial economic stake in the outcome should be able to have its own rights adjudicated vis-a-vis both parties); Innis, Speiden & Co. v. Food Machinery Corp., 2 F.R.D. 261, 264 (D. Del. 1942) (Pursuant to Rule 24(a) and (b), court allowed motion of exclusive licensee to intervene as plaintiff in suit by patentee charging defendant with patent infringement); cf. Precision Shooting Equipment, Inc. v. Allen, 199 U.S.P.Q. 459, 461 (E.D. Ill. 1978) (Pursuant to Fed. R. Civ. P. 24(b), licensee allowed to intervene as plaintiff challenging validity of patent.)

Amgen argues, however, that the motion is not timely since Ortho has been fully aware of the pendancy of this action since "well prior to February, 1988"; a preliminary injunction has been issued; and the parties agreed to consent to jurisdiction before a magistrate, at the urging of the trial court, because of the need for a decision before the end of 1989. Amgen also points out that no discovery has been taken of Ortho.

Fed. R. Civ. P. 24 dictates that any motion to intervene must be timely. United States v. Metropolitan District Comm., 865 F.2d 2, 5 (1st Cir. 1989), citing NAACP v. New York, 413 U.S. 345, 365 (1973). The First Circuit has established four factors for evaluating the timeliness issue: (i) the length of time the prospective intervenors knew or reasonably should have known of their interest before they petitioned to intervene; (ii) the prejudice to existing parties due to the intervenor's failure to petition for intervention promptly; (iii) the prejudice the prospective inventors would suffer if not allowed to intervene; and (iv) the existence of unusual circumstances militating for or against intervention. Id. The court will examine each of these factors separately as follows:

(i) The delay in filing the motion to intervene is substantial. Ortho does not dispute that it knew about the

Massachusetts action at least thirteen months before it filed its motion to intervene. Nonetheless, it justifies this delay in two ways. First, it argues that it was forced into the present controversy by the grant of GI's motion to join it in the California action and by the denial of Ortho's motion to dismiss the action on February 6, 1989. Docket 137 p. 2. Second, counsel argues that because of the case backlog in Massachusetts, he could reasonably have expected that the action in California would be tried before the action in Massachusetts and Ortho could not have anticipated that the parties would consent to an expedited trial before a magistrate. However, these justifications do not excuse the delay. Parties having knowledge of the pendency of litigation which may affect their interests sit idle at their peril. Narragansett Indian Tribe v. Ribo, Inc., 868 F.2d 5, 7 (1st Cir. 1989) (belated invention was not allowed where intervenors, believing the lawsuit was frivolous, expected it would be dismissed). If Ortho believed that its interests would not be adequately represented by Amgen, it is hard to see why those interests were no less implicated by the original filing of the suit, the motion for preliminary injunction and the various motions for summary judgment, than the actual trial. The fact that Ortho did not expect the parties to consent to a trial before a magistrate does not justify the delay. See also United Nuclear Corp. v. Cannon, 696 F.2d 141, 143 (1st Cir. 1982) ("United Neclear Corp.") (the fact that ongoing settlement discussions eventually collapsed did not justify waiting seven and one half months to move to intervene since the intervenor "was surely aware that settlement negotiations often collapse").

ii. Amgen and defendants oppose intervention because of their concern that the need for Ortho to engage in discovery, and to take discovery of Ortho, would postpone the trial date of August 7, 1989 by at least a couple of months. Defendants point out that Ortho has just produced a half a million documents in the California action, which would have

to be reviewed. Even Ortho expressed doubt that it could be ready for trial by August 7, 1989. Ordinarily, a delay of a few months would not be prejudicial, particularly in a case of this importance and complexity. However, a preliminary injunction has issued requiring defendant GI to put profits from the sale of erythropoietin into an escrow account, and as the trial court has stated, the outcome of this case is not only of great significance to the parties involved, but involves a matter of great public interest because erythropoietin is "an extraordinarily valuable medicine that promises marked relief from renal failure." Docket 88. Therefore, a delay of even a few months would prejudice the parties, and the public.

iii. Ortho has not demonstrated it would be substantially prejudiced by a denial of the motion to intervene. It argues that Amgen does not adequately represent its interests because of the animosity between the two companies, and points to Amgen's purported failure to adequately represent Ortho before the Food and Drug Administration ("FDA"). Ortho also argues that as a result of Amgen's failure to meet these obligations before the FDA, Amgen will become a competitor in the sale of erythropoietin once regulatory approvals are obtained, and will have every reason to exclude Ortho from that market. Docket 137, p. 7.

A prospective intervenor faces a presumption of adequacy when it has the same ultimate goal as a party. United Nuclear Corp., 696 F.2d at 144. To overcome that presumption, petitioner ordinarily must demonstrate adversity of interest, collusion, or nonfeasance. The First Circuit has looked at three factors on adequacy of representation:

> (1) Are the interests of a present party in the suit sufficiently similar to that of the absentee such that the legal arguments of the latter will undoubtedly be made by the former; (2) is that

> present party capable and willing to make such arguments; and (3) if permitted to intervene, would the intervenor add some necessary element to the proceedings which would not be covered by the parties in the suit?

Id., citing Blake v. Pallan, 554 F.2d 947, 954-955 (9th Cir. 1977).

Here, Amgen's ultimate goal in defending the '008 patent, and in challenging the '195 patent appears to be identical to Ortho's. The fact that there are disputes under the license agreements does not diminish Amgen's strong incentive to protect the patent. Amgen has talented trial counsel from both Boston and Chicago aggressively seeking through temporary restraining orders, preliminary injunctions and an expedited trial schedule, to prosecute its patent rights. It has also vigorously pressed its claims in related proceedings before the International Claims Commission. Further, the court is hard-pressed to credit Ortho's arguments that it is not contented with Amgen's representation with respect to the '008 patent since it relied on Amgen for over three months in this action, and fought to be dismissed from the California action.

Ortho was unable to articulate any specific way in which it would be prejudiced by denial of its application. First, it points out that it manufactures some of its own erythropoietin which has different characteristics than the erythropoietin manufactured by Amgen and therefore it will be prejudiced if it is not permitted to defend itself against defendants' claim of infringement. Further, it argues that because of the difference in the characteristics of its erythropoietin, it should be able to litigate the meaning of the claims in the '195 patent with respect to homogeneity. However, to the extent Ortho can show it was not adequately

represented by Amgen concerning erythropoietin produced by Ortho, it will not be barred from raising this issue either in the California action or elsewhere. Second, Ortho expresses concern that since there is such animosity between Amgen and it, if there is a settlement, Amgen will not protect Ortho's license rights. However, settlement at this point seems speculative[2] and to the extent Amgen violates the exclusive license agreements, Ortho can resort to litigation, as it has in the past.

iv. Because of the importance of erythropoietin, and the pending preliminary injunction, there are unusual circumstances militating against intervention and for speedy trial.

CONCLUSION

The Court recommends that the motion to intervene be denied.[3]

---

[2]At the hearing, counsel for Amgen stated that it had invited Ortho to settlement discussions, but declined to promise that Ortho would be invited to all settlement discussions.

[3]Any objections to this Report and Recommendation must be filed with the Clerk of Court within ten days of receipt of the Report and Recommendation must identify the portion of the Report and Recommendation to which objection is made and the basis for such objection. Any party may respond to another party's objections within ten days after service of the objections. Failure to file objections within the specified time waives the right to appeal the district court's order. United States v. Escoboza Vega, 678 F.2d 376, 378-379 (1st Cir. 1982); United States v. Valencia-Copete, 792 F.2d 4, 6 (1st Cir. 1986).

PATTI B. SARIS
United States Magistrate

D-1

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

AMGEN, INC.,

Plaintiff,

v.

CIVIL ACTION NO. 87-2617-Y

CHUGAI PHARMACEUTICAL CO., LTD., et al.,

Defendants.

REPORT AND RECOMMENDATION RE: MOTION OF ORTHO PHARMACEUTICAL CORPORATION TO INTERVENE IN THIS ACTION PURSUANT TO RULES 24(a)(2) AND 24(b)(2), FED. R. CIV. P. (DOCKET 116)

May 26, 1989,

This report and recommendation is approved and the motion of Ortho Pharmaceutical Corporation to intervene is denied.

William G. Young
District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ORTHO PHARMACEUTICAL CORP., CILAG GESELLSCHAFT M.B.H., CILAG N.V., CILAG LTD., CILAG S.A.R.L., CILAG G.M.B.H., CILAG S.P.A., CILAG-MEDICAMENTA Lda., JOHNSON & JOHNSON S.A. (CILAG DIVISION), CILAG AB, CILAG AG, and CILAG AG INTERNATIONAL, Plaintiffs, vs. GENETICS INSTITUTE, INC., Defendant.	Civil Action No.

PLAINTIFFS' MOTION PURSUANT TO RULE 42(a) FED.R.CIV.P., FOR CONSOLIDATION OF THIS ACTION WITH ANOTHER CASE PRESENTING COMMON QUESTIONS OF FACT AND LAW

Ortho Pharmaceutical Corp. and the other plaintiffs in this action, all of which are wholly-owned subsidiaries of Johnson & Johnson, respectfully move this Honorable Court for an order consolidating this action with a pending case, Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. and Genetics Institute, inc., C.A. No. 87-2617-Y (the "Amgen Action") pursuant to Rule 42(a), Fed.R.Civ.P., for the

following reasons and grounds, which are more fully set froth in an accompanying affidavit and memorandum . . . .

August 16, 1991,

Motion allowed.

William G. Young
District Judge

F-1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. CHUGAI PHARMACEUTICAL CO., LTD. and GENETICS INSTITUTE, INC., Defendants.	Judge William G. Young Civil Action No. 87-2617-Y
ORTHO PHARMACEUTICAL CORP., et al., Plaintiffs, v. GENETICS INSTITUTE, INC., and AMGEN, INC., Defendants.	Civil Action No. 91-12174-Y

PLAINTIFFS' EMERGENCY MOTION FOR CERTIFICATION UNDER RULE 54(b)

December 24, 1992.

Certification under Fed.R.Civ.P. 54(b) is

unnecessary. This Court favors an expedited appeal and since Civil Action 91-12174-Y is now at an end and the order of consolidation is vacated.

William G. Young,
District Judge

Supreme Court, U.S.
FILED
AUG 7 1995
CLERK

No. 95-35

(2)

In the Supreme Court of the United States

OCTOBER TERM, 1995

ORTHO PHARMACEUTICAL CORP.,
PETITIONER,
v.
GENETICS INSTITUTE, INC. AND AMGEN INC.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT GENETICS INSTITUTE, INC.'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Court of Appeals for the Federal Circuit correctly interpreted a series of interrelated license agreements to find that the petitioner's patent license was nonexclusive and that, under well established law, a nonexclusive licensee such as the petitioner lacked standing to sue for patent infringement.

STATEMENT PURSUANT TO RULE 29.1

The respondent Genetics Institute, Inc., is affiliated with American Home Products Corporation.

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In the
Supreme Court of the United States

OCTOBER TERM, 1995

No. 95-35

ORTHO PHARMACEUTICAL CORP.,
PETITIONER,

v.

GENETICS INSTITUTE, INC. AND AMGEN INC.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE
FEDERAL CIRCUIT

RESPONDENT GENETICS INSTITUTE, INC.'S BRIEF IN OPPOSITION

The respondent Genetics Institute, Inc. ["Genetics"] respectfully requests that this Court deny the petition for writ of certiorari.

STATEMENT

The petitioner incorrectly states that the Federal Circuit "effectively overruled" this Court's decision in *Independent Wireless Telegraph Co.* v. *Radio Corporation of America*, 269 U.S. 459 (1926). Both courts below fully acknowledged the validity of the relevant precedents — including *Independent Wireless* — and applied them to the facts of this case. The courts below did not rule explicitly (or "effectively") that an exclusive field-of-use licensee lacked standing to sue for patent infringement within

its licensed field. Rather, both courts concluded that the particular agreements at issue in this case did not make Ortho Pharmaceutical Corp. ["Ortho"] an exclusive patent licensee in the field in which the alleged infringement occurred.

The petitioner's characterization of this complex series of license agreements is thus at odds with the findings of both lower courts. Far from presenting the important and clear-cut issue of law asserted by the petitioners, the decisions below present no more than a factual dispute about the proper characterization of a particular arrangement between private parties, and as such does not warrant this Court's review.

The essential ruling of the Court of Appeals in disposing of the petitioner's claim was its determination that whatever patent rights were granted to Ortho were non-exclusive, and that whatever arguably exclusive rights were granted to Ortho were not patent rights, and thus could not confer standing in this patent suit:

> Ortho commingles its consent from Kirin-Amgen to sell EPO abroad . . . with the rights it received from Amgen under the U.S. patent to use the '008 technology. U.S. patent '008 provides no rights respecting the product EPO *per se*. . . . With respect to Ortho's right to sell unpatented EPO abroad, the [district] court correctly held that Ortho's right was not a proprietary right arising from the '008 patent. Indeed, Amgen itself had no right to sell EPO abroad by reason of its obtaining the '008 patent and, thus, could not license that right to Ortho as an incident of patent ownership. With respect to rights under the '008 patent, Ortho had only a nonexclusive right to use the '008 invention at one location in the United States. Thus, considering only this right, Ortho is a bare, that is, nonexclusive, licensee and has no standing to bring or join a suit for infringement against Genetics.

[App. A at A-15 (footnote omitted)]

Finally, Ortho fails to advert to an alternative ground for the ruling below, which effectively disposes of this suit without reference to the issues Ortho raises here.

A. *Factual Background*

Erythropoietin ["EPO"] is a hormone that stimulates the synthesis of red blood cells in bone marrow. As both lower courts recognized, Amgen Inc.'s United States Patent No. 4,703,008 [the "'008 patent"] does not cover the EPO product itself. [App. A at A-2; App. B at B-5]. Rather, the '008 patent claims a purified and isolated DNA sequence encoding human EPO and host cells transformed or transfected with a DNA sequence in a manner that allows the host cells to express EPO. In essence, the patent covers certain products (machines or starting materials) used to manufacture EPO, but does not cover the EPO product manufactured by those machines or starting materials.

In 1984, three years prior to the issuance of the patent, Amgen and Kirin Brewery Company established a joint venture, Kirin-Amgen, Inc. At the same time, Amgen, as owner of the then-pending application for the '008 patent, assigned certain rights to Kirin-Amgen. [App. A at A-2 - A-3].

In 1985, Amgen and Kirin-Amgen entered into separate Product License Agreements (PLAs) with Ortho. Those PLAs addressed much more than the '008 patent: they granted not only certain patent rights under the '008 patent, but also certain *foreign* patent and *contractual (i.e.,* non-patent) rights.

Section 2.01(b) of Ortho's license agreement with Amgen provided the basis for Ortho's claim of standing before the Federal Circuit:

> AMGEN, having received the consent of Kirin Brewery Co., Ltd., hereby grants to ORTHO but not AFFILIATES, an exclusive license, except as against AMGEN's rights under this AGREEMENT in the LICENSED TERRITORY, to make EPO in one location

> in the United States for use and sale outside the LICENSED TERRITORY but not including China and Japan. . . .

[App. A at A-4].[1] The agreement defined the LICENSED TERRITORY as the United States. [*Id.* at A-4 - A-5].

The PLA executed by Ortho and Amgen also contained section 8.02, entitled "Infringement by Third Parties," which provided:

> AMGEN shall have the right, but not the obligation, to bring, defend, and maintain any appropriate suit or action. . . . In the event AMGEN fails to take actions with respect to such matters within a reasonable period, not more than six (6) months, following receipt of such notice and evidence, ORTHO shall have the right, but not the obligation, to bring, defend, and maintain any appropriate suit or action.

[App. A at A-15 - A-16].

From Kirin-Amgen, Ortho obtained (1) an "exclusive license" to *sell* throughout the world (except for the United States, China, and Japan) EPO manufactured by using the inventions claimed in the '008 patent for all human uses except diagnostics, and (2) the right to use the inventions claimed in the '008 patent to *manufacture* EPO in one location in the United States for *sales everywhere outside* the United States

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[1] Section 2.01(a) of the Amgen PLA provided:

> AMGEN hereby grants to Ortho but not AFFILIATES, except as hereinafter provided, an exclusive license to make in one location, have made and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENSED TERRITORY.

As discussed below, Ortho expressly abandoned reliance on Section 2.01(a) before the Federal Circuit and, thus, only Section 2.01(b) of the PLA is presently at issue in this case. *See* Note 6, *infra*.

(except China and Japan) for all human uses except diagnostics. [App. B at B-5 - B-6].

On October 27, 1987, the date the '008 patent issued, Kirin-Amgen assigned the patent to Amgen and Amgen brought suit for infringement against Genetics. The trial was bifurcated into liability and damages phases. After a year and a half of discovery, the trial on liability was scheduled to begin on August 7, 1989. [App. C at C-4]. On March 17, 1989, Ortho moved to intervene in that action. [*Id.*]. That motion was denied on grounds of untimeliness and because Ortho's interests regarding liability were adequately represented by Amgen. [App. C at C-1 and C-12]. Ortho did not appeal that decision.

Following a bench trial on liability, certain claims of the '008 patent were found to be valid and enforceable and to be infringed by Genetics' use of the '008 invention to manufacture EPO in the United States. *Amgen Inc.* v. *Chugai Pharmaceutical Co., et al.*, 13 U.S.P.Q.2d 1737 (D. Mass. 1989).[2] The Federal Circuit affirmed the judgment on the '008 patent on interlocutory appeal. *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir.) *cert. denied*, 502 U.S. 856 (1991).[3]

Ortho and its European licensees then filed suit against Genetics in the district of Massachusetts seeking damages for lost profits on foreign sales of the unpatented EPO product.[4] Ortho's suit was consolidated with Amgen's suit. Both the patentee Amgen and Genetics filed motions to dismiss or for summary judgment against Ortho on the grounds that Ortho lacked standing.

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[2] The district court also found that Genetics' infringement of the '008 patent was not willful and that Genetics' patent relating to EPO was valid and infringed by Amgen. *Id.* at 1739.

[3] The Federal Circuit, however, reversed the district court's judgment relating to the validity of Genetics' EPO-related patent.

[4] Ortho also filed suits against Genetics' licensee in various European countries seeking the same damages for the same transactions under foreign patents relating to EPO.

B. *The District Court's Decision on Standing*

The district court granted the motions to dismiss Ortho for lack of standing.[5] In so doing, the court expressly recognized the rule of *Independent Wireless* that an exclusive patent licensee has standing to sue for patent infringement in its stated area of exclusivity. [App. B at B-11 - B-12]. The district court also recognized, however, that "a mere non-exclusive licensee has no standing to sue for infringement," and that it was therefore necessary to examine the precise language of the license agreements to determine whether those agreements actually granted Ortho exclusive use of any portion of the '008 patent. [App. B at B-12 - B-13]. The court correctly noted that this issue should be determined by the substance of those agreements rather than by their use of the label "exclusive license." [App. B at B-5].

The district court then turned to Ortho's argument that section 2.01(b) of the Amgen PLA granted Ortho an exclusive field-of-use license to use the '008 patented inventions in the United States to make EPO for the purpose of sale abroad.[6] After considering in detail the various provisions of Ortho's PLAs with both Amgen and Kirin-Amgen, the district court concluded that, although Ortho may have received an exclusive contractual right under those agreements to export the *unpatented* EPO product, it did not receive an exclusive right to use any portion of the '008 patent itself; thus, the district court concluded that Ortho was not an exclusive licensee with standing to sue for any infringement of the '008 patent. [App.

[5] Prior to the ruling by the district court, the underlying Amgen/Genetics litigation was settled. [App. A at A-18].

[6] The district court had also rejected Ortho's argument that standing could be premised on Section 2.01(a) of its PLA with Amgen. [App. B at B-15 - B-17]. Ortho expressly abandoned this Section 2.01(a) argument on appeal. [App. A at A-12].

B at B-17 - B-21].[7] On this basis,[8] the district court granted Genetics and Amgen's motion.

C. *The Federal Circuit's Decision on Standing*

After independently examining the variously intertwined provisions of the Amgen and Kirin-Amgen PLAs, the Federal Circuit unanimously affirmed the district court's conclusion that Ortho's only exclusive right was the right to sell EPO abroad, which is not a right under the '008 or any other United States patent. Instead, the exclusive right to sell the unpatented EPO product abroad was a *contractual* right. In short, the Federal Circuit concluded that Ortho's section 2.01(b) argument for standing erroneously "commingles its consent from Kirin-Amgen to sell EPO abroad ... with the rights it received from Amgen under the U.S. patent to use the '008 technology." [App. A at A-14].

Repeatedly relying on *Independent Wireless* [*see, e.g.*, App. A at A-11, A-16, and A-17], the Federal Circuit first

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[7] In its petition Ortho contends that "the district Court stated: '[Ortho holds] an "exclusive license" to use the invention claimed in the '008 patent for the manufacture of EPO ... in the U.S. ... for the sale outside the U.S.'." As support for its contention, Ortho cites App. B at B-16. At that point in its opinion, however, the district court was reciting the language of the PLA; the quoted language was not a finding by the district court that the PLA granted an exclusive field-of-use under the '008 patent. As the district court expressly noted, "both PLA's use the words 'exclusive license' to describe the rights Ortho obtains from Kirin-Amgen and Amgen respectively. Whether these words have the legal effect of making Ortho an exclusive licensee under patent law, however, is a question the Court resolves *infra*. ..." [App. B at B-5].

[8] Although Ortho argued to the Federal Circuit (and continues to argue to this Court) that the basis for the district court's decision was the "bizarre and unprecedented theory" that a field-of-use license "somehow 'exceeds the scope of the ... patent' and therefore cannot provide a basis for standing." Petition at 10, the Federal Circuit properly recognized that this argument is based on a fundamental misreading of the district court's opinion. "Contrary to Ortho's argument, the court held only that the provision respecting foreign sales of EPO was a contract right, not that the agreement was unenforceable against Amgen." [App. A at A-15 n. 7].

noted that the question of licensee standing was a highly fact-dependent inquiry:

> Co-plaintiff standing is determined by whether or not the licensee acquired proprietary rights in the patent under the contract with the patentee. . . . To resolve the issue of standing, we must examine the licensing agreement to determine whether the parties intended to effect a transfer of proprietary rights to the licensee as an incident to protection of its interests.

[App. A at A-12]. In making this factual inquiry the Federal Circuit accepted as true all material allegations of Ortho's complaint, which it construed in Ortho's favor. [App. A at A-13].

The Federal Circuit next turned to a detailed examination of the various license agreements. The Federal Circuit noted that it was "undisputed" that, with respect to patent rights, Ortho's implied license to use the '008 invention in one location in the United States "was nonexclusive inasmuch as Amgen had the right to license others to do the same." [App. A at A-14]. As the Federal Circuit summarized Ortho's argument, "Ortho concedes this point but argues that its additional right to sell EPO abroad as provided in paragraph (b) is an exclusive field of use of the '008 technology which provides standing." [*Id.*]

The Federal Circuit rejected this argument because of Ortho's failure to distinguish between the exclusive contract (*i.e.*, non-patent) rights that Ortho received and the nonexclusive U.S. patent rights it received.

> U.S. Patent '008 provides no rights respecting the product EPO *per se*. Moreover, a U.S. patent grants rights to exclude others from making, using, and selling the patented invention only *in the United States*. . . . With respect to Ortho's right to sell unpatented EPO

> abroad, the [district] court correctly held that Ortho's right was not a proprietary right arising from the '008 patent.

[App. A at A-14 - A-15] (emphasis in original).

Based on the various provisions of the PLAs, the Federal Circuit ultimately concluded that,

> with respect to rights under the '008 patent, Ortho had only a nonexclusive right to use the '008 invention at one location in the United States. Thus, considering only this right, Ortho is a bare, that is, nonexclusive, licensee and has no standing to bring or join a suit for infringement against Genetics.

[App. A at A-15].[9]

REASONS WHY THE PETITION SHOULD BE DENIED

A. *Neither the decision below nor the record raises the Questions Presented in the petition*

Ortho suggests that this case presents the "important question" of "whether the holder of an exclusive license to practice a patent in a particular field-of-use has standing to sue for acts of infringement in that field-of-use. . . ." Petition at 3. In fact, however, the petitioner's proffered question was not presented at all by the facts of this case. To the contrary,

[9] Ortho now urges that this decision was at odds not only with *Independent Wireless*, but also with a series of decisions in the Federal Circuit and other courts of appeal. Ortho, however, failed to seek *in banc* reconsideration by the Federal Circuit, which is the usual manner in which intra-circuit conflicts within the Federal Circuit are clarified. *See* Fed.R.App. P. 40 (providing that a petition for rehearing may be filed when a party believes that the appeals court has "overlooked or misapprehended" a point of law); Federal Circuit Practice Note to Rule 40 (authorizing the filing of a suggestion for rehearing *in banc*).

both the district court and the Federal Circuit accepted and applied the rule of law that the petitioner asks this Court to reaffirm on certiorari — that is, that exclusive field-of-use licensees do have standing.

The legal right of an exclusive field-of-use licensee to sue for infringement was never at issue below. Rather, under the facts of this case, both lower courts found that because Amgen retained the right to use the '008 patent and the unfettered privilege to sublicense that right, Ortho was not an exclusive licensee. Well settled legal principles make it clear that if Ortho is a nonexclusive licensee, it does not have standing to sue for patent infringement; the petitioner does not contend otherwise. Not only is the Federal Circuit's decision thus not contrary to *Independent Wireless*, it endorses the central tenet of that case, as stated by the petitioner itself: a field-of-use licensee shall have standing to sue if, and only if, "the license confers exclusive rights in that particular field" under the patent. Petition at 3. As both lower courts found, Ortho's license does not.

Moreover, there can be no doubt that the Federal Circuit considered itself bound by (and to be applying) *Independent Wireless*. Its opinion repeatedly cites, quotes, and relies on this Court's opinion in that case. [*See, e.g.*, App. A at A-11, A-16, and A-17]. Indeed, the Federal Circuit has consistently applied *Independent Wireless* elsewhere, both before and after its decision in this case. *See, e.g., Abbott Laboratories* v. *Diamedix Corp.*, 47 F.3d 1128, 1131 (Fed. Cir. 1995); *Rite-Hite Corp.* v. *HMH Co.*, 56 F.3d 1538, 35 U.S.P.Q.2d 1065, 1074 (Fed. Cir. June 15, 1995). Thus, the contention by the petitioner that the Federal Circuit has effectively "overruled" *Independent Wireless* is baseless.

The petitioner further urges that this case presents the question whether the measure for standing for a field-of-use licensee is the exclusivity of its rights with respect to (a) the entirety of the "use" right covered by the patent, or (b) the particular field-of-use where the acts of infringement occurred. Yet, that question was not at issue in this case, either.

The '008 patent gave Amgen the right to exclude Genetics from using the patented technology in the United States; the *patent* conferred no rights regarding the sale of the unpatented EPO product abroad. Thus, the patent was found to be infringed by Genetics' use of the '008 invention *in the United States*, where Ortho's patent rights are nonexclusive. Indeed, Ortho expressly "concede[d]" that its implied right to use the '008 invention was nonexclusive. [App. A at A-14].

The essence of Ortho's argument below was that certain exclusive *non-patent* rights granted to Ortho by Kirin-Amgen could create a field of exclusivity within Ortho's admittedly nonexclusive *patent* rights from Amgen. Both lower courts correctly rejected this argument under the facts of this case. As both lower courts concluded, Ortho's exclusive rights were not derived from the '008 patent, but rather were the product of commingling Ortho's contract rights and its nonexclusive patent rights. [App. A at A-14; App. B at B-21].

Thus, the Questions Presented proffered by the petitioner are simply not raised by the facts of this case or the holdings of the courts below.

B. *The petition asks this Court to reinterpret complex and fact specific licensing provisions despite consistent interpretation by both courts below*

The licensing provisions at issue are complex, interrelated, and highly fact specific, involving two different licensors, both with different sets of U.S. and foreign patent and non-patent rights to license. Two courts have already worked their way through these licensing provisions and arrived at the same factual conclusion: that the license grant to Ortho was nonexclusive under the '008 patent. In arriving at that factual conclusion, the Federal Circuit did not purport to establish a new rule of law or, indeed, any rule of general applicability beyond the specific facts of this case.

Ortho now asks this Court to work through these provisions yet a third time. There is, however, nothing in the petition

or in the decisions below to indicate that this Court would arrive at anything other than the same conclusion: that, under the licensing provisions at issue in this case, Ortho received only a nonexclusive license under the '008 patent. This highly fact-specific determination by the courts below is not worthy of review by this Court. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 336 U.S. 271, 275 (1949) ("a court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional show of error").[10]

C. *The petition ignores the unique role of the Court of Appeals for the Federal Circuit*

Although the petitioner suggests that its petition should be granted "[b]ecause the Federal Circuit hears all appeals in patent cases," Petition at 16, the Federal Circuit's exclusive jurisdiction over patent appeals in fact provides an additional reason for denying the petition. Indeed, the Federal Circuit was established in large part to bring expertise and uniformity to patent law. *See* House Rep. No. 97-312, 97th Cong., 1st Sess. (1981) at 20-23.

In this case, the Federal Circuit did precisely what it was supposed to do: it took general principles as mandated by this Court and applied them to a case-specific tangle of facts. The result reached by the Federal Circuit in this matter upholds all of the policy considerations underlying the law of standing in patent infringement suits, including the policies:

- that the patent owner (here, Amgen) has the paramount interest in selecting the forum for defending its patent;

[10] Even if the points raised in the petition were valid and worthy of certiorari, they would not dispose of this case. This matter would need to be remanded for consideration of section 8.02 of the PLA, not reached by the Federal Circuit. In that section of the PLA, Ortho bargained away to Amgen any right Ortho may have had to bring a suit against infringers, *even if* Ortho had standing.

- that the accused infringer (here, Genetics) should not be subjected to multiple suits resulting from the same act; and
- that economic injury alone is insufficient to support standing in a nonexclusive licensee.

See, A.L. Smith Iron Co. v. *Dickson*, 141 F.2d 3, 6 (2d Cir.1944) (L. Hand, J.) [*quoted favorably in* App. A at A-9 - A-10]. *See also, Site Microsurgical Systems, Inc.* v. *Cooper Companies, Inc.*, 797 F.Supp. 333, 337 n.8, 24 U.S.P.Q.2d 1463, 1466 n.8 (D. Del. 1992); *Schneider (Europe) AG* v. *SciMed Life Systems, Inc.*, 28 U.S.P.Q.2d 1225, 1229 (D. Minn. 1993).

D. *The Federal Circuit had alternative grounds for its decision not included in the petition*

In the final paragraph of its opinion, the Federal Circuit held that:

> Ortho does not claim it was a necessary or indispensable party to Amgen's suit, did not appeal the denials of intervention therein, and did not appeal the order deconsolidating this suit from Amgen's. Moreover, the parties advised the Court at the hearing that the Amgen/Genetics litigation has been settled. Thus, Ortho has effectively consented and concurred to suit in the name of the patentee alone.

[App. A at A-18].

Thus, the Federal Circuit found that, even if Ortho's arguments for co-plaintiff standing had any merit, those arguments have been waived by Ortho's effective consent and concurrence in Amgen's lawsuit. This fully independent, alternative ground for the Federal Circuit's decision was not included in the petition for certiorari and thus presents yet another reason for its denial.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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No. 95-35

IN THE
Supreme Court of the United States

OCTOBER TERM, 1995

ORTHO PHARMACEUTICAL CORP.,
Petitioner,

v.

GENETICS INSTITUTE, INC. AND AMGEN INC.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF ON BEHALF OF AMGEN INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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STATEMENT PURSUANT TO SUPREME COURT RULE 29.1

Amgen Inc. has no parent companies and no subsidiaries (except wholly-owned subsidiaries).

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ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
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RESPONDENT AMGEN'S BRIEF IN OPPOSITION

Respondent Amgen Inc. ("Amgen") hereby opposes the Petition for Writ of Certiorari filed by Ortho Pharmaceutical Corp. ("Ortho") in this case.

STATEMENT OF THE CASE

This case involves the straightforward interpretation and application of specific contract provisions to determine the Petitioner's rights under a series of interrelated license agreements. Although somewhat complex, the interpretation of the

agreements posed no novel or difficult issues for the district court or the court of appeals below, both of which reviewed the facts in detail and both of which arrived at the same legal conclusion.

Ortho's Petition for Writ of Certiorari improperly mischaracterizes the facts of the case and the holdings below in an unavailing attempt to invent an "important question" of law where no such question exists. Ortho's assertion that the court of appeals has somehow re-written the law of standing in patent cases by "effectively overruling" this Court's decision in *Independent Wireless Telegraph Co.* v. *Radio Corp. of America*, 269 U.S. 459 (1926) is wrong because all that the court of appeals in fact did was to hold that Ortho was a non-exclusive licensee under the license agreement and as such lacked standing to sue. The factual prerequisite upon which Ortho's petition is laid, namely that Ortho holds an exclusive field-of-use license under the patent in suit, is incorrectly presumed as a given by the Petition. Yet such a finding is the very issue decided against Ortho by both courts below. The district court and the court of appeals each properly concluded that the rights of Ortho under the license agreement simply fall far short of the requisite ownership interest in the patent required for standing to sue. Both lower courts reached their consistent conclusions by applying ordinary principles of contract law to the facts, in complete harmony with this Court's guiding precedents, including *Independent Wireless*.

A. *The Patent In Suit and the Relevant License Provisions*

The patent at issue in this case, United States Patent No. 4,703,008 ("the '008 patent") issued on October 27, 1987, and is solely owned by Amgen. This patent claims DNA sequences that encode human erythropoietin ("EPO"), as well as vectors and host cells transformed or transfected with such

DNA sequences. This same patent was held valid (in part) and infringed in the prior appeal from this action, *Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, ___ U.S. ___, 112 S.Ct. 169 (1991). The '008 patent does *not* claim the EPO product or any process[1] for making such an EPO product. Rather, it covers the biologic materials that are used to produce recombinant EPO.

On September 30, 1985, before the '008 patent issued, Amgen and Ortho entered into a Technology License Agreement and a Product License Agreement (collectively, the "License Agreements") directed to three therapeutic products produced by recombinant DNA technology: EPO, human interleuken-2 (IL-2), and hepatitis B vaccine, as well as processes for their manufacture.[2] The two other recombinant products, IL-2 and hepatitis B vaccine, are neither covered by the '008 patent nor otherwise involved in this action.

The principal grant of rights in the License Agreements is found in Paragraph 2.01, which contains two subparagraphs, (a) and (b). Subparagraph (a) grants to Ortho:

> an exclusive license to make in one location, have made, and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENSED TERRITORY.

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[1] In prior litigation involving the '008 patent, the Federal Circuit affirmed the decision that the '008 patent does not cover a process for producing EPO. *Amgen, Inc.* v. *U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990).

[2] For purposes related to this petition, the License Agreements differ only as to the time period of their effect. The Technology License Agreement became effective on September 30, 1985, and remained in effect through about August, 1988, when the Product License Agreement superseded it. The pertinent terms of the agreements are identical.

In Subparagraph (b), Amgen grants to Ortho:

> an exclusive license, except as against Amgen's rights under this AGREEMENT in the LICENSED TERRITORY, to make EPO in one location in the United States for use and sale outside the LICENSED TERRITORY. . . .

The license granted under subparagraph 2.01(b) is not specifically directed or limited to *patent* rights.[3] Critically, Amgen's own right to make EPO in the licensed territory is expressly reserved.

In the License Agreements, Amgen and Ortho expressly allocated the right to bring suit against third parties for infringement of patent rights covered by the License Agreements. Amgen specifically retained "the right . . . to bring, defend and maintain any appropriate suit or action" for infringement. (A. 15).[4] Pursuant to Paragraph 8.02 of the License Agreements, only "[i]n the event Amgen fails to take action with respect to such matters within a reasonable period, not more than six (6) months, following receipt of such notice and evidence, Ortho shall have the right . . . to bring, defend and maintain any appropriate suit or action." Further, "[a]bsent an agreement between the parties to jointly bring any action or suit hereunder and share the expenses thereof, any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof." (A. 16.) The License Agreements do not grant Ortho any unconditional right to bring suit for infringement under the licensed '008 patent. Instead, Ortho's limited right to sue and collect damages from third

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[3] In contrast to Subparagraph 2.01(a), which specifically grants rights under "LICENSED PATENTS" and other intellectual property rights.

[4] All appendix designations herein refer to the printed decisions of the courts below, as annexed to Ortho's Petition.

parties is expressly contingent on Amgen electing *not* to bring suit within a reasonable period.

Here, Amgen *did* bring a patent infringement suit against Genetics Institute (hereinafter "GI"), promptly after the issuance of the '008 patent in 1987. Amgen neither requested nor received any assistance from its licensee, Ortho, in support of that infringement action. Amgen bore the entire expense of litigating the validity and infringement of the '008 patent, including a three month trial on the merits, a subsequent appeal to the Federal Circuit by both parties, and a response to a petition for writ of certiorari by GI. On March 5, 1991, after three and one half years of litigation, at great effort and expense borne solely by Amgen, the Federal Circuit affirmed the validity and GI's infringement of the '008 patent. *Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc.*, 927 F.2d 1200 (Fed. Cir. 1991). Certiorari was denied. 112 S.Ct. 169 (1991).

B. *The District Court Decision*

After Amgen prevailed in the liability phase of its infringement suit against GI, Ortho filed a separate patent infringement action against GI seeking damages for the same infringing acts. (B. 3). In an attempt to bootstrap a position with respect to standing, the licensee Ortho named Amgen, the patent owner, as a defendant in the new lawsuit, and then sought to realign Amgen as an involuntary plaintiff (B. 4). Amgen moved to dismiss Ortho's amended complaint for failure to state a claim, on the ground that Ortho lacked standing to bring its action. In granting the motion, the district court specifically found that the license grant under Paragraph 2.01(a) and (b) is non-exclusive with respect to the claimed subject matter of the '008 patent (B. 21), and that Ortho therefore has no standing to enforce the '008 patent.

Noting that it is well settled that a non-exclusive licensee has no standing to sue for infringement (B. 11), the district court properly held that one test for exclusivity is whether or not the licensor has promised explicitly or implicitly not to grant any additional licenses for the "patented invention" to third parties. (B. 12, 13). The district court also correctly observed at the outset that it is not dispositive that the License Agreements merely use the term "exclusive license." (*Id.*)

The district court concluded that Paragraph 2.01 reserved for Amgen the right to make EPO in the United States, and "does not contain any implied promise by Amgen not to further sub-license its right to manufacture EPO in the U.S. using the inventions claimed under the '008 patent." (B. 16, 17). Thus, the district court concluded that Ortho's license under the '008 patent is not exclusive as to this licensed patent right, and Ortho lacks standing, as a matter of law, to sue Genetics Institute for infringement of the '008 patent. (B. 18, 23).

In disposing of Ortho's argument that GI's infringement occurred within the limited area of Ortho's claimed exclusivity, the district court correctly noted that the '008 patent claims cover only the DNA sequences, vectors and transfected host cells used to manufacture EPO, and do not cover the EPO product itself. (*Id.*) Thus, the *patent* rights licensed to Ortho are the right to make and use the patented precursor materials, in the United States, to make unpatented EPO. Amgen expressly reserved these same rights to itself under the same patent. (B. 21). Ortho urged that the additional qualification of the granting language ("to make EPO *for sale abroad*") created an exclusive patent right distinct from Amgen's co-extensive right to make EPO in the United States using the inventions of the '008 patent.

The district court ruled that no such exclusive patent right exists. Contrary to Ortho's mischaracterization of that ruling, the district court did *not* find that Ortho was granted an exclusive

patent right of the expansive scope it asserted, or that the license is unenforceable as an unlawful extension of the '008 patent. Rather, the district court held simply that Ortho's territorial exclusivity arises solely from *contract* rights, and not from any license under the '008 patent. The district court correctly concluded that, since Ortho has no exclusive patent rights, it has no standing to sue Genetics Institute for infringement of the '008 patent. (B. 21).

C. *The Court of Appeals' Affirmance*

As previously noted, Paragraph 2.01(b) of the License Agreement permits Ortho to make EPO in the United States for sale abroad. On appeal to the Federal Circuit, Ortho abandoned its argument of standing based on Paragraph 2.01(a) (*see* A. 12) but renewed its claim that Paragraph 2.01(b) constitutes an exclusive grant under the '008 patent. The Federal Circuit rejected this contention and affirmed the district court's ruling that Ortho's license under the '008 patent is non-exclusive.

The Federal Circuit noted at the outset that, under well-settled law, standing to sue for patent infringement is reserved to the patent owner, except in extraordinary circumstances "as where the patentee is the infringer, and cannot sue himself." (A. 6, *quoting Waterman* v. *McKenzie*, 138 U.S. 252, 255, 11 S.Ct. 334, 335 (1891)). An exclusive licensee seeking enforcement of the patent can sue, if at all, only together with the patentee or in the name of the patentee. (A. 7). A holder of a non-exclusive patent license, however, suffers no legal injury from infringement and, thus, has no standing to bring suit or even to join in a suit with the patentee. (*Id.*, *citing Western Elec. Co.* v. *Pacent Reproducer Corp.*, 42 F.2d 116, 118 (2d Cir.), *cert. denied*, 282 U.S. 873 (1930). The test of patent license exclusivity, and therefore co-plaintiff standing,

is whether or not the licensee possesses "beneficial ownership of a right to prevent others from making, using or selling *the patented technology*." (A. 10, 11) (emphasis added).

The Federal Circuit thus began its analysis by examining what portion of the license "in fact concerns the '008 patent." (A. 13). The appellate court agreed with the district court's conclusion that the grant in Paragraph 2.01(b) ". . . to make EPO in the United States . . ." necessarily carried the implied right to use the inventions of the '008 patent to do so. (A. 14). Recognizing that this granting clause expressly reserved to Amgen a co-extensive right under the '008 patent to make EPO in the United States, the Federal Circuit rejected Ortho's attempt to differentiate its limited license rights in the patent from Amgen's retained ownership rights. The *additional* contractual right to sell EPO abroad, as claimed by Ortho (A. 14), was held not to create an exclusive field-of-use patent right sufficient to confer standing:

> Ortho commingles its consent from Kirin-Amgen to sell EPO abroad . . . with the rights it received from Amgen under the U.S. patent to use the '008 technology. U.S. patent '008 provides no rights respecting the product EPO *per se*. . . . With respect to Ortho's right to sell unpatented EPO abroad, the [district] court correctly held that Ortho's right was not a proprietary right arising from the '008 patent.

(A. 15). Thus, the Federal Circuit concluded that Ortho holds only a bare, non-exclusive license to the invention claimed in the '008 patent. (*Id.*)

The Federal Circuit also rejected Ortho's alternate suggestion that the right to sue clause of Paragraph 8.02 conferred standing upon Ortho despite Ortho's lack of any exclusive right in the '008 patent. The requirement that a licensee have

beneficial ownership of at least some part of the patentee's proprietary rights, the court stated, cannot be overcome by a contractual allocation. (A. 16, 17, *citing Crown Die & Tool Co.* v. *Nye Tool & Machine Works*, 261 U.S. 24, 44 (1923). Since Ortho has only a non-exclusive right in the '008 patent, the Federal Circuits concluded, "the right to sue clause has no effect in this case." (A. 16.)

Finally, the Federal Circuit noted that Ortho had not claimed to be a necessary or indispensable party to Amgen's action against GI, did not appeal the denials of intervention in Amgen's litigation, and did not appeal the order deconsolidating its suit from Amgen's suit (A. 18). The Federal Circuit concluded from these facts that Ortho had "effectively consented and concurred to suit" in the name of Amgen, the patentee, alone. *Id.* Ortho has not raised this alternate ground for the appellate court's decision as an issue for review by this Court.

SUMMARY OF THE ARGUMENT

Two lower courts have reviewed Ortho's rights under the License Agreements, and both courts have concluded that Ortho holds only a non-exclusive license under the '008 patent in suit. Accordingly, under well-settled law properly applied by the courts below, Ortho does not have standing to sue for infringement of that patent. The questions presented for review by Ortho are mere hypotheticals that have no relation to the facts of this case. Because Ortho's patent rights fall short of those required to confer standing, the decisions of the courts below raise no conflict with past decisions of this Court (including *Independent Wireless*) and other courts defining the circumstances under which an exclusive patent licensee may bring suit to enforce the licensed patent.

REASONS FOR DENYING THE PETITION

A. *Ortho's "Questions Presented" Are Not Fairly Raised by the Facts of This Case*

Ortho's fundamental mischaracterization of its non-exclusive rights under the '008 patent in suit creates the risk of a mistaken belief that the questions presented raise issues appropriate to be decided by this Court. Ortho *presumes* in its Petition that it is an exclusive licensee under the '008 patent, even though both lower courts held that it was only a non-exclusive licensee. Ortho's charge that the Federal Circuit overruled this Court's decision in *Independent Wireless* is founded on this factually incorrect premise. In truth, the Federal Circuit properly applied, and certainly did not overrule, *Independent Wireless* in holding that a non-exclusive licensee has no standing to sue for infringement of the patent.

Legal standing to sue for patent infringement derives from the claimed patent rights granted to the patent owner. *Waterman* v. *McKenzie*, 138 U.S. at 255. Both lower courts correctly reviewed the License Agreements to determine what rights Ortho received under the '008 patent. In this case, the '008 patent claims the DNA sequences, vectors and host cells used to make EPO, and the patent does not extend to the EPO itself produced by using those patented materials. Simply restating the Federal Circuit's decision, Ortho lacks standing to sue GI for patent infringement because Ortho holds no proprietary right to exclude others from practicing the "patented invention" claimed by the '008 patent. Standing to sue for patent infringement cannot be "conferred" by what an infringer does later with an unpatented product, or by any additional contractual rights which Ortho may have received from Amgen.

In the License Agreement which defines the scope of Ortho's rights under the '008 patent, Amgen clearly retained the right to practice the "patented invention" itself, the right to grant

additional sub-licenses to practice the "patented invention," and the right to exclude others from the practice of the "patented invention," if necessary, by suing infringers. The Federal Circuit clearly held:

> With respect to patent rights, Ortho had an implied license to use the '008 invention in one location in the United States. It is undisputed that the right was non-exclusive inasmuch as Amgen had the right to license others to do the same. (A. 12).

Such a reservation of rights precludes both exclusivity and standing to Ortho under the long established precedent of *Waterman* v. *McKenzie* and its progeny. The Federal Circuit correctly noted that Ortho had conceded this point.

Ortho's license under the '008 patent is not exclusive within a field-of-use. The "exclusive field-of-use" repeatedly claimed by Ortho applies to a territory outside the U.S. granted to Ortho for sale of the *unpatented EPO product*. Ortho's right to sell EPO outside the United States is a contract right and not a patent right licensed under the '008 patent. Thus, Genetics Institute's ultimate disposition in a foreign country of the unpatented EPO product resulting from the infringing use in the United States of the DNA sequences, vectors and host cells claimed in the '008 patent is irrelevant to Ortho's standing to sue under that patent.

The district court and the Federal Circuit both correctly interpreted the License Agreements as conveying a non-exclusive license under the '008 patent. Paragraph 2.01(a), which expressly grants rights to Ortho in "Licensed Patents", is subject to Amgen's own right to grant further sub-licenses of the right to make EPO in the United States using the patented DNA sequences, vectors and host cells of the '008 patent. Ortho conceded this point in the appellate court. (A. 14). Para-

graph 2.01(b), which does not expressly grant any license under any patent, but which the courts below reasonably interpreted to create an implied license to use the patented inventions of the '008 patent "to make EPO in the United States", is expressly subject to Amgen's right to do the same. Only by reaching *beyond* the scope of the '008 patent claims, by commingling the right to sell EPO abroad granted to Ortho separately, can Ortho define a right which it does not share with Amgen. That right, however, is only a *contract* right as against Amgen, is not founded on the '008 patent, and therefore cannot create legal standing to sue as an exclusive patent licensee. (A. 14, 15).

The Federal Circuit has now twice considered the scope of the '008 patent as it bears on legal standing to sue. In the prior appeal from Amgen's International Trade Commission action, the Federal Circuit ruled that the scope of the '008 patent claims may not be extended from the claimed DNA sequences, vectors and host cells to encompass the *process* by which those precursor materials are used to make recombinant EPO. *Amgen, Inc* v. *U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990). In the decision below, the Federal Circuit correctly rejected Ortho's contention that the '008 patent claims could be stretched even farther to encompass not only the process of making EPO using the patented materials, but the resulting EPO *product* as well.

B. *Ortho's Petition Fails to Justify This Court's Review*

Ortho's petition fails to raise any of the special and important reasons of Supreme Court Rule 10 which justify this Court's review. Contrary to Ortho's misrepresentations, the decision below does not conflict with the decisions of other United States Courts of Appeals or of this Court. *See* Supreme Court Rule 10.1(a). When viewed without the distorting lens of

Ortho's false premise that it holds an exclusive right to a patented field-of-use, the decisions of both the district court and the court of appeals below are entirely consistent with all of the relevant past decisions of this court and inferior courts. The *Independent Wireless* decision trumpeted by Ortho was *not* violated by the courts below. Rather, *Independent Wireless* presented a different fact situation in which the licensee was found to have an exclusive field-of-use license in the patented invention. Based on the finding that the license was exclusive, this Court there held that the exclusive licensee could sue for infringement by joining the patentee. The clear point of factual departure in comparison with the present case is the absence of an exclusive license in the patented invention.

The cases following *Independent Wireless* cited by Ortho to support its standing argument also all involved exclusive rights in a field-of-use of a patented invention, and not of the unpatented product resulting from the licensed practice of the patent in suit. In each of *Western Electric Co., Inc.* v. *Pacent Reproducer Corp.*, 42 F.2d 116 (2d Cir. 1930); *Sanofi, S.A.* v. *Med-Tech Veterinarian Products, Inc.*, 222 USPQ 143 (D.Kan. 1983); and *Pratt & Whitney Co.* v. *United States*, 153 F.Supp. 409, 114 USPQ 246 (Ct. Cl. 1957), a field-of-use license was exclusive because it defined an exclusive use *of the patented invention*.[5] What the holdings of these cases reveal is *not* that the decision below is a departure from a "previously unbroken line of authority" as incorrectly alleged by Ortho (Ortho Petition at 21), but that without the fundamental premise of an exclusive license to practice at least some defined portion of the patented invention, *Independent Wireless* and its progeny are factually not on point.

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[5] The fourth case cited by Ortho, *Brunswick Corp.* v. *United States*, 19 USPQ2d 1702 (Ct. Cl. 1991), is not a field-of-use case at all. Rather, that case involved the grant of an exclusive right to *make* and *sell* the patented invention to one particular customer.

The Federal Circuit decision here is wholly consistent with the holdings in these cases that require an exclusive license, and in no way departs from the accepted and usual course of judicial proceedings so as to call for the exercise of this Court's supervisory power. *See* Supreme Court Rule 10.1(a). Moreover, the decision of the Federal Circuit below upholds the important policies underlying the law of standing in patent infringement cases set forth by Judge Learned Hand in *A.L. Smith Iron Co.* v. *Dickson*, 141 F.2d 3, 6 (2d Cir. 1944), including the paramount interest of the patent owner in selecting the forum for defense of his patent rights, and the protection of the accused infringer from multiple suits resulting from the same act of infringement.

While Ortho complains that it was injured by GI's infringement, economic injury to a licensee is not sufficient to overcome these important policy considerations and confer standing to sue. *Id.* When, as here, a licensee holds less than an exclusive right under the patent, the "[p]ractice of the invention by others may indeed cause him pecuniary loss, but it does him no legal injury." *Western Elec. Co.* v. *Pacent Reproducer Corp.*, 42 F.2d at 118.

Perhaps most importantly, this case presents no new and important question of federal law which should be settled by this Court. *See* Supreme Court Rule 10.1(c). Rather, this case involves the interpretation of clauses in license agreements negotiated between the patent owner and its licensee. Of necessity, this case is fact-specific, hinging not only on the particular language of the contract between the parties, but also on the scope of the '008 patent licensed. No important question of federal law arises from such facts.

C. *Even If Ortho Had Sufficient Rights Under the '008 Patent To Confer Standing, Ortho Contractually Bargained Away Any Such Right to Bring Suit*

Finally, even if Ortho were assumed to have sufficient rights under the '008 patent to confer standing to sue for patent infringement, Ortho bargained away that right to sue to its licensor, Amgen, under Paragraph 8.02 of the License Agreements.

The License Agreements provide Amgen with the right of first option to sue infringers of the '008 patent regardless of the nature of the infringing acts. Amgen exercised that right by suing Genetics Institute after the '008 patent issued. Although the lower courts did not reach this ground for dismissing Ortho's suit, none of the facts necessary to determine this legal question are in dispute, and the judgments below may be upheld on the basis of this provision of the License Agreements alone. *See, e.g., Panaview Door & Window Co.* v. *Van Ness et al.*, 135 F.Supp. 253, 107 USPQ 31 (S.D.Cal. 1955) (district court dismissed an *exclusive* licensee's infringement action for want of capacity to sue where the agreement reserved for the licensor the unconditional right to bring suit, with the licensee having the subordinate right to sue should the licensor decline to do so).

Amgen has the right in the first instance to sue infringers, and, having elected to do so, Amgen alone is entitled to the damages awarded for such infringement.

CONCLUSION

Ortho has shown no special and important reason for this Court to exercise its discretionary power of review here. The fundamental factual premise underlying the questions presented in the petition is unsupported by the facts of the case.

The district court and the court of appeals below reviewed the uncontested facts, applied them to the contract in question, and reached the same legal conclusion. Ortho holds no exclusive patent license under the '008 patent. Ortho's petition for a writ of certiorari should be denied.

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No. 95-35 (4)

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

ORTHO PHARMACEUTCAL CORP.,

Petitioner,

—v.—

GENETICS INSTITUTE, INC. and AMGEN, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY

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No. 95-35

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ORTHO PHARMACEUTICAL CORP.,

Petitioner,

—v.—

GENETICS INSTITUTE, INC.
and AMGEN, INC.,

Respondents.

On A Petition For A Writ of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITIONER'S REPLY BRIEF

Reply Argument

Respondents cannot reconcile *Independent Wireless*[1] and the decision below. Their basic argument -- that *Independent Wireless* retains continued vitality because the Federal Circuit purported to apply it -- misses the point entirely. It glosses over the important issues that are presented for this Court's review.

This Court should grant certiorari *not* because the decision below overlooks *Independent Wireless* -- it doesn't -- but rather because it eviscerates *Independent Wireless* in the

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1 *Independent Wireless Telegraph Co. v. Radio Corp. of America*, 269 U.S. 459 (1926).

guise of applying it. It does so by requiring, as a condition for licensee standing, that the license be exclusive not only in the *relevant field-of-use*, but also in the *totality* of the "use" right. Because field-of-use licenses, by definition, *never* confer exclusive rights in the *totality* of the "use" right, this is a test for standing that field-of-use licensees can never meet.

1. Respondents Cannot Identify Anything "Nonexclusive" About Ortho's Rights In The Relevant Field-Of-Use

Respondents describe the decision below as applying *Independent Wireless*. But they are unable to find anything in that decision, or in the License Agreement, that could support the characterization of Ortho's rights as non-exclusive *in the relevant field-of-use*. Like the court below, they characterize Ortho's rights as non-exclusive only by looking *outside* the relevant field-of-use.

For example, Amgen contends that Ortho's rights are non-exclusive because it, Amgen, supposedly retained the right to use the patented invention and to grant additional sublicenses for its use. Amgen Brief at 10-11. Although Amgen reserved such rights *outside* the relevant field-of-use, it did not do so within that field.

The district court's findings on this point are clear. The district court found that Amgen reserved certain rights *outside* Ortho's field-of-use, including the right to: (a) use the patented inventions to make EPO for sale "*in the U.S.* for *dialysis and diagnostic purposes*," App. B at B-16-17 (emphasis in original), and (b) to "grant additional licenses to use the patented '008 inventions in the U.S. to make EPO for use or sale *in the U.S.* for *dialysis and diagnostic purposes*." *Id.* (emphasis in original).

Significantly, the district court found no similar reservation of rights by Amgen *within* the relevant field-of-use. In fact, the district court found precisely the opposite. The district court repeatedly described Ortho's rights within the relevant field as "exclusive." *See, e.g.*, App. B at B-17. Moreover, it found that paragraph 2.01(b) of the License Agreement (which defines Ortho's exclusive field-of-use) "clearly . . . precludes Amgen from licensing to any third parties the right to [use the patented invention] to manufacture EPO . . . for sale abroad." *Id.* On appeal, Amgen did not challenge these findings, and the court of appeals did not disturb them.

These fact findings are plainly correct. The License Agreement is "straightforward" (Amgen Brief at 1), and it does not contain any reference to the rights that Amgen now says it reserved in the relevant field-of-use.

Respondents place great emphasis on a statement from the court of appeals' decision, to the effect that Amgen retained "the right to license others" to "use the '008 invention in one location in the United States." App. A at A-12. This statement, however, is not specific to the relevant field-of-use. In light of the district court's unchallenged finding that the License Agreement "clearly . . . precludes" Amgen from licensing others to practice the patent in that particular field, App. B. at B-17, the court of appeals' statement can only be understood as referring to a right that Amgen did retain, *i*.e., the right to grant additional licenses *outside* the relevant field.

Like the court below, respondents can describe Ortho's rights as non-exclusive only by focussing on the "use" right as an undifferentiated whole, instead of on the relevant field-of-use. Thus, Amgen argues that Ortho's generalized right "to make EPO in the United States" -- *not* Ortho's right in the specific field-of-use -- is non-exclusive because of "Amgen's

right to do the same."[2] Amgen Brief at 12. Similarly, Genetics Institute offers the conclusory assertion that Ortho's generalized "right to use the '008 invention" is non-exclusive. GI Brief at 11. These arguments miss the point. The basis for Ortho's standing is not a generalized "right to use the '008 invention," or a generalized right "to make EPO." Rather, it is Ortho's exclusive right to use the patented invention in a particular field that is spelled out with specificity in paragraph 2.01(b) of the License Agreement.

Like the court below, respondents incorrectly treat the "use" right under the '008 patent as a generalized, undifferentiated whole, without focusing with the specificity that *Independent Wireless* requires on exclusivity in the relevant field-of-use. That approach cannot be reconciled with *Independent Wireless*.

2. *Respondents' Emphasis On The Right To "Sell" Unpatented EPO Abroad Is A Smokescreen*

Both respondents hide behind a smokescreen. They confuse the right to *sell* unpatented EPO *abroad* (which is not

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2 Even if Amgen had reserved the right to practice the '008 patent in Ortho's field-of-use -- which it clearly did not do -- that would not deprive Ortho of standing to sue Genetics Institute for infringement in Ortho's exclusive licensed field. A patent license must be exclusive as against third-parties but it need not be exclusive *as against the licensor* in order for a licensee to have standing to enforce the patent against third-party infringers. *Western Electric Co. v. Pacent Reproducer Corp.*, 42 F.2d 115, 120 (2d Cir.), *cert. denied*, 282 U.S. 873 (1930); *Research Frontiers, Inc. v. Marks Polarized Corp.*, 290 F. Supp. 725, 727 (E.D.N.Y. 1968).

the basis for Ortho's standing) with the right to *use* the '008 invention *in the United States* for a particular, defined purpose (which *is* the basis for Ortho's standing). Thus, Amgen pretends that Ortho's field-of-use "applies to a territory outside the U.S. . . . for *sale* of the *unpatented* EPO product." Amgen Brief at 11. Similarly, Genetics Institute pretends that Ortho sought standing on the basis of a right to *sell* "unpatented EPO abroad." GI Brief at 11.

Respondents know better. Ortho clearly described the relevant field-of-use in the court below, when it stated:

> The basis for Ortho's standing is an "exclusive" license . . . to *use the '008 inventions* [*i.e.*, the patented DNA sequences and host cells] *in the U.S.* [for a particular purpose, *i.e.*] to make EPO in the U.S. for use and sale outside the U.S.

App. G. at G-4. Ortho's briefs in the court below left no doubt on this point. *See, e.g.*, App. G. at G-1, 6, 13, 17 and 18. Given this emphasis, it is irresponsible for respondents to suggest that the basis for Ortho's standing is a right to *sell* unpatented EPO, abroad or anywhere else.

Unfortunately, respondents are not alone in resorting to this smokescreen; the Federal Circuit made the same error in its decision. App. A at A-14-15.

3. *The Federal Circuit Never Has Recognized Standing For Parties With Exclusive Field-Of-Use Licenses*

Genetics Institute cites *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995), and *Abbott Laboratories*

v. Diamedix Corp., 47 F.3d 1128, 1131 (Fed. Cir. 1995), as evidence that the Federal Circuit follows *Independent Wireless*. *See* GI Brief at 10. Those cases are not on point.

In both cases, the Federal Circuit cited *Independent Wireless* merely for the uncontroversial proposition that "exclusive licensees" have standing to sue for infringement. Neither case addresses the more particularized issue that is presented here, *i.e.*, whether licensees whose rights are exclusive in a *particular field-of-use* also have standing to sue.

The Federal Circuit has not endorsed that principle in any case. The only Federal Circuit case addressing this issue is the decision below.

4. Amgen's ¶ 8.02 Argument Is Specious

In opposing the petition, Amgen advances a theory that neither the district court nor the court of appeals accepted. It argues that the judgment below "may be upheld" on the basis of paragraph 8.02 of the License Agreement, which Amgen reads as giving it alone the right to sue for infringement. *See* Amgen Brief at 15.

Amgen raised the same argument in the district court and in the court of appeals, each time without success. *See* App. A at A-16; App. B. at B-23 at n.16. This alternative argument, already rejected by two lower courts, provides no reason for denying certiorari.

There is a good reason why two lower courts refused to accept Amgen's argument on this point: Contrary to Amgen's contention, paragraph 8.02 expressly recognizes Ortho's right to sue in circumstances like those presented here. Indeed, that paragraph imposes upon Amgen a contractual

obligation to assist Ortho in suing infringers. It requires Amgen to "execute all papers and . . . perform such other acts as may be reasonably required" to assist Ortho in bringing such suits. *See* App. G. at G-18. License terms of this type do "not preclude [an exclusive licensee] from bringing suit" against a third-party infringer. *Brunswick Corp. v. United States*, 22 Cl.Ct. 278, 282 (Ct.Cl. 1991).

5. *Genetics Institute's "Waiver" Theory Does Not Provide A Reason For Denying Certiorari*

Genetics Institute also offers a fallback position. It cites *dicta* in the decision below, which it incorrectly casts as an alternative basis for the lower court's ruling. Relying on this *dicta*, Genetics Institute argues that Ortho "waived" its right to sue for infringement in its exclusive field-of-use. *See* GI Brief at 13. This "waiver" theory is devoid of merit. The undisputed facts, recited below, show that Ortho at all times was vigorous in trying to enforce its rights:

a) Ortho tried to intervene in *Amgen v. Chugai* before trial in the liability phase of that action, only to be denied intervention on the grounds that Amgen could adequately protect Ortho's interests with respect to *liability* (but not with respect to damages). *See* App. C at C-12.

b) Once the liability phase of *Amgen v. Chugai* ended, Ortho promptly brought this action. No defenses based on the statute of limitations or laches were asserted. Nor could these defenses be asserted consistent with Rule 11, Fed.R.Civ.P.

c) Within weeks after it commenced this action,

Ortho sought and obtained an order consolidating this action with the *Amgen v. Chugai* case, so that discovery in the two actions could be coordinated and the cases could be tried together. *See* App. E at E-2.

d) After the district court dismissed this action for lack of standing, Ortho promptly moved for leave to appeal pursuant to Rule 54(b), Fed.R.Civ.P. In response to that motion, the district court entered an order deconsolidating the two cases in order to permit "an expedited appeal" by Ortho. *See* App. F at F-2. Ortho then pursued an appeal in the Federal Circuit.

This undisputed evidence refutes any suggestion that Ortho "waived" its right to recover from Genetics Institute for its infringing acts in Ortho's exclusive licensed field.

6. The Public Importance Of This Case

Respondents do not challenge the public importance of permitting exclusive field-of-use licensees to sue for infringement in the area of an exclusive license, under the standards set forth in *Independent Wireless*. The lower court's departure from those standards -- and its creation of a new test that exclusive field-of-use licensees can never meet -- warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

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APPENDIX G: Ortho's Brief on Appeal In the Court Below (Excerpts)

STATEMENT OF THE CASE

A. INTRODUCTION

This is an appeal from a district court judgment dismissing a patent infringement case at the pleading stage for lack of standing. That decision has now been officially reported, sub. nom. Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., at 808 F. Supp. 894 (D. Mass. 1992).

The plaintiff-appellant, Ortho Pharmaceutical Corp. ("Ortho"), has an exclusive license to use in the U.S. the inventions claimed in U.S. Patent No. 4,703,008, i.e., certain products of recombinant DNA technology, to make a naturally occurring hormone which controls the production of red blood cells, erythopoietin ("EPO"), for use and sale outside the U.S. (A 628-29, A 144-45).

This Court has already ruled that the defendant-appellee Genetics Institute, Inc. ("Genetics") has infringed the '008 patent. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ 2d 1016 (Fed. Cir.), cert. denied, ___ U.S. ___, 112 S. Ct. 169 (1991). Moreover, Genetics has admitted that its infringement occurred in Ortho's exclusive licensed field. (A 194).

Under settled law, Ortho has standing as the holder of an exclusive license to sue for infringement in its exclusive licensed field. However, the district court injected irrelevant issues into the standing inquiry -- and then made them the basis for denying Ortho standing.

In analyzing standing, the district court focused on the

field-of-use restriction in Ortho's license which permits Ortho to use the patented inventions in the U.S. for the limited purpose of making EPO for use and sale outside of the U.S., and held (incorrectly) that this restriction exceeded the scope of the patent. (Op. at 24). The court then adopted an over-simplified and incorrect rule: that a license which exceeds the scope of the patent is "not exclusive under patent law as against third party infringers." (Id.) Based on these findings, the district court concluded "as a matter of law" that Ortho does not have standing as an exclusive licensee to sue for infringement in its licensed field. (Id.) As the district court conceded, no other case has ever applied this approach in evaluating standing.

This decision is not only unprecedented -- it is wrong as a matter of law.

Contrary to the district court's holding, exclusive field-of-use licenses such as Ortho's do not "exceed the scope of the patent." What is more, licenses that do exceed the scope of the patent are enforceable against third party infringers unless there is proof that the license unreasonably restrains competition in a relevant market. This record contains no such proof.

Even more basically, the issues that the district court focused on are not the test for determining standing. Ortho's standing is measured by the exclusivity of its license -- not by whether provisions in its license agreement "exceed the scope of the patent."

Thus, the dismissal of Ortho's complaint for lack of standing was legal error, and it should be reversed.

B. THE FACTS RELEVANT TO ORTHO'S STANDING

1. The '008 Patent

The patent in suit, U.S. Patent No. 4,703,008, issued to Dr. Fu-Kuen Lin on October 27, 1987. Dr. Lin assigned his patent rights to his employer, Amgen, Inc. ("Amgen").

The claims in the '008 patent cover a purified and isolated DNA sequence encoding human erythropoietin ("EPO") and host cells transformed or transfected with a DNA sequence in a manner allowing the host cells to express EPO. Amgen, 927 F.2d at 1206-07, 18 USPQ 2d at 1021; Amgen, Inc. v. U.S. Int'l Trade Comm'n, 902 F.2d 1532, 1533-34, 14 USPQ 2d 1734, 1736 (Fed. Cir. 1990).

EPO is a hormone that is naturally produced and present in humans and other animals. It controls the synthesis of red blood cells in bone marrow. It is useful in treating patients suffering from anemia. The claims in the '008 patent cover products, i.e., DNA sequences and transfected host cells, that are useful in making recombinant EPO. They do not cover EPO itself. Amgen v. U.S. Int'l Trade Comm'n, 902 F.2d at 1533-34, 14 USPQ 2d at 1736.

2. Ortho's Rights Under the '008 Patent

Ortho's rights under the '008 patent derive from a Technology License Agreement and a Product License Agreement (collectively, the "License Agreements") that Ortho entered into on September 30, 1985 with defendant Amgen. (A 618 et. seq. and A 134 et. seq.). When the License Agreements were signed, the application for the '008 patent was still pending.

The basis for Ortho's standing is an "exclusive license" under ¶ 2.01(b) of the License Agreements to use the '008 inventions in the U.S. to make EPO for use and sale outside the U.S. As the district court found:

> [S]ection 2.01 of the Amgen-Ortho PLA [Product License Agreement] . . . grants Ortho "an exclusive license" to use the inventions claimed in the '008 patent for the manufacture of EPO in one location in the U.S. . . . for use and sale outside the U.S. (excluding China and Japan).

(Op. at 18).

The terms of both License Agreements are identical in pertinent part. Section 2.01 of each License Agreement states as follows:

> ARTICLE 2
>
> LICENSE
>
> 2.01 GRANT
>
> (b) AMGEN . . . hereby grants to ORTHO . . . an exclusive license, except as against AMGEN's rights under this AGREEMENT in the LICENSED TERRITORY [defined in ¶ 1.14 as the United States, its territories and possessions], to make EPO in one location in the United States for use and sale outside the LICENSED TERRITORY but not including China and Japan.

(A 628-29, A 144-45) (emphasis added). The district court correctly recognized that this provision not only licenses Ortho to use the patented inventions in the U.S. to make EPO for sale abroad, but also that it "clearly . . . precludes Amgen from licensing to any third parties the right to manufacture EPO in the U.S. under the '008 patent for sale abroad." (Op. at 18).

The only relevant difference between the two License Agreements relates to the time period when each Agreement is in effect. Pursuant to its express terms, the Technology License Agreement became effective on September 30, 1985, and remained in effect until regulatory authorities in a "major country" approved recombinant EPO for human use. When regulatory authorities in France granted such approval in August 1988, the Product License Agreement then came into effect. (A 693; A 137, 172).

3. Genetics' Infringement of the '008 Patent is Within the Scope of Ortho's Exclusive License

Following this Court's ruling in Amgen, 927 F.2d 1200, 18 USPQ 2d 1016, that Genetics infringed claims 2, 4 and 6 of the '008 patent by using the patented inventions in the United States, Genetics admitted that its acts of infringement consisted of using the '008 inventions in the United States to make EPO for sale to its European licensee, Boehringer-Mannheim G.m.b.H. ("Boehringer"), for distribution by Boehringer in Europe. (A 194). Genetics also admitted that Boehringer paid it $34,100,000 for the EPO that Genetics produced in the United States by its infringing acts. (Id.)

C. PRIOR PROCEEDINGS IN THIS CASE AND IN THE RELATED ACTION BY AMGEN AGAINST GENETICS

1. Ortho's Complaint In This Action

Ortho commenced this action against Genetics in August 1991 to recover damages that Ortho suffered as a result of Genetics' adjudicated infringement of the '008 patent. Ortho alleged in its complaint, among other things, that the License Agreements gave it an exclusive license to use the '008 inventions to make EPO in one location in the U.S. for sale outside the U.S. and that Genetics had infringed the '008 patent by using the patented inventions in the U.S. in Ortho's exclusive licensed field. (A 78).

Eleven European affiliates of Ortho were also named as plaintiffs in the Ortho action. These entities hold non-exclusive licenses from Ortho to distribute EPO that is made using the '008 inventions in various European countries.

On October 15, 1991, Ortho amended its complaint as of right under Rule 15(a), Fed.R.Civ.P., to name Amgen as a defendant as required by Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459 (1926). (A 222). Ortho also moved at that time for an order realigning Amgen as a plaintiff. (A 750). That motion was denied on November 14, 1991. (A 232).

2. The Prior Adjudication That GI Infringed The '008 Patent

Immediately after Ortho filed this action, the district court consolidated this case upon Ortho's motion with another suit pending in the same court, Amgen, Inc. v. Chugai

Pharmaceutical Co., Ltd. and Genetics Institute, Inc., Civil Action No. 87-2617-Y (the "Amgen action").

The Amgen action also charged Genetics with infringing the '008 patent, and this Court held in Amgen that claims 2, 4 and 6 of the '008 patent were not invalid, were enforceable and were infringed by Genetics. Amgen, 927 F.2d 1200, 18 USPQ 2d 1016.

3. Ortho's Motion To Intervene in the Amgen Action

In March 1989, more than two years before it commenced this action, Ortho had moved to intervene in the Amgen action under Rule 24, Fed.R.Civ.P. (A 234 et seq.). In response to that motion, neither Amgen nor Genetics disputed Ortho's standing to sue Genetics for infringement of the '008 patent. Amgen, however, argued that intervention could delay a trial on liability and that it (Amgen) could adequately represent Ortho's interests in the liability phase. The district court accepted those arguments, and in May 1989 it denied Ortho's motion to intervene. (A 241). See Op. at 7, n.6.

Ortho commenced this action shortly after this Court issued its decision in Amgen, bringing the liability phase of that case to a conclusion.

4. Defendants' Motion For Summary Judgment Dismissing Ortho's Complaint

Instead of answering Ortho's complaint in this action, Genetics and Amgen moved at the outset for summary judgment dismissing the complaint for lack of standing. Genetics (and Amgen) argued that Ortho's rights in the U.S. under the '008 patent were "limited" and thus "fall . . . short of the

'exclusivity' required to confer 'co-plaintiff' standing." (A 395). Genetics (and Amgen) also argued that paragraph 8.02 of the License Agreements allocated the right to sue infringers exclusively to Amgen. Genetics (but not Amgen) argued that the district court lacked subject matter jurisdiction because some of Ortho's alleged lost profits relate to sales abroad. Finally, Genetics also argued that prior pending actions in California and Germany required dismissal of Ortho's claims.

D. THE DISTRICT COURT'S DECISION DENYING ORTHO STANDING

On December 3, 1992 the district court issued a Memorandum and Order dismissing Ortho's Amended Complaint for lack of standing.

After summarizing the facts, the district court outlined the applicable standards for determining whether a licensee has standing to sue for patent infringement. The district court stated that a "mere nonexclusive licensee" lacks standing to sue for infringement. (Op. at 12). The court recognized, however, that the rule is different for "exclusive licensees":

> "An exclusive licensee generally has standing to sue for infringement against anyone operating without the stated authority in the stated area of exclusivity."

(Op. at 11). The district court also stated that:

> an exclusive license can be created by a grant of exclusivity based solely upon geographic, time, or field-of-use limitations.

(Op. at 13). In addition, the district court stated:

> [I]t should be stressed that the test for exclusivity is not whether the license is exclusive as against the licensor, but rather whether the licensor has promised explicitly or implicitly not to grant additional licenses to third parties.
>
> * * *
>
> Thus, if the terms of the [License Agreements] preclude Amgen from granting further licenses under the patent within the stated area given to Ortho, then Ortho is an "exclusive licensee" with the legal capacity to sue for patent infringement within the stated area.

(Op. at 13, 15) (emphasis in original).

In applying these basic principles, the district court recognized that:

> [S]ection 2.01 of the Amgen-Ortho PLA [Product License Agreement] . . . grants Ortho "an exclusive license" to use the inventions claimed in the '008 patent for the manufacture of EPO in one location in the U.S. for . . . use and sale outside the U.S. (excluding China and Japan).

(Op. at 18). Moreover, in applying the established "test for exclusivity" (Op. at 13), the court recognized that the License Agreements preclude Amgen from granting any additional licenses to third parties in this licensed field. Thus, the court held that (id.):

> [C]learly, this provision [¶2.01(b)] precludes

> Amgen from licensing to any third parties the right to manufacture EPO in the U.S. under the '008 patent for sale abroad.

Coupled with the district court's finding that Genetics has used the '008 inventions in the U.S. to make EPO for sale abroad (Op. at 6), these findings compel one conclusion: that Ortho has standing to sue for acts of infringement in Ortho's exclusive field-of-use. This should have ended the inquiry.

However, the district court did not stop there. Instead, in analyzing standing, it went on to address the following issue (Op. at 22):

> whether the field-of-use restriction in the license Amgen granted to Ortho [which gives Ortho the right to use the '008 inventions in the U.S. to make EPO for use and sale outside the U.S.] exceeds the scope of the '008 patent.

Apparently, the district court considered this issue pertinent to standing on the oversimplified and incorrect theory that a "field-of-use limitation . . . [that] exceeds the scope of the patent . . . is not enforceable under patent law." (Op. at 21).

The district court never explained where this "patent law" is or what it is. It acknowledged that Genetics and Amgen "fail[ed] to offer any case law" suggesting that Ortho's field-of-use restriction exceeds the scope of the patent. (Op. at 20). The court also stated that Genetics and Amgen "do not cite, and this Court has not found, any case" suggesting that standing should depend on whether a field-of-use restriction "exceeds the scope of the patent." (Op. at 21).

In analyzing whether Ortho's license "exceeds the scope

of the patent," the district court applied a rigid, formalistic approach. It analogized the patented invention (i.e., the DNA sequences and transfected host cells) to "'machines' or 'starting materials' used for manufacturing EPO." (Op. at 22). It ignored the point that patented processes or materials are often used, particularly in the field of bio-technology, to produce non-patented products, and proceeded to adopt a per se rule that "a license to use a patented machine to make a certain unpatented product for sale abroad . . . exceeds the scope of the patent on the machine." (Op. at 23).

This holding overrules sub silentio a long line of cases which establish that similar field-of-use licenses do not exceed the scope of a patent. It is also in irreconcilable conflict with Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 24 USPQ 2d 1173 (Fed. Cir. 1992), which holds that per se rules cannot be used in determining whether license restrictions will render a plaintiff's patent rights unenforceable. Under Mallinckrodt, there must be proof of anticompetitive effects and unreasonableness before a license can be found unenforceable. Id., 976 F.2d at 706, 24 USPQ 2d at 1178.

Ignoring these cases, the district court concluded (incorrectly) that the field-of-use limitation in Ortho's license -- which "restricts Ortho's use of the patented DNA sequences and host cells to the making of EPO for sale abroad" (Op. at 23) -- "exceeds the scope of the '008 patent." (Op. at 24). After making this incorrect finding, the district court then made an inexplicable leap: It denied Ortho standing on this basis.

The court summarized its reasoning in a flawed syllogism. It held (incorrectly) that a field-of-use license to use a patented invention in the U.S. to make an unpatented product for sale abroad "exceeds the scope of the patent" (Op. at 24); that a license which exceeds the scope of the patent is "not

exclusive under patent law as against third party infringers" (id.); and that "as a matter of law" the holder of such a license accordingly "lacks standing as an exclusive licensee" to sue for infringement. (Id.) The court summarized its holding as follows (id.):

> [T]his Court holds that a field-of-use license which grants an exclusive license to use the inventions claimed under the '008 patent (the DNA sequences and transfected host cells) in the U.S. to make an unpatented product (EPO) for sale abroad exceeds the scope of the '008 patent. Thus, the exclusive license Ortho asserts, that is, to use the patented products to manufacture EPO in the U.S. for export, is . . . not exclusive under patent law as against third party infringers. Hence, as a matter of law, Ortho lacks standing as an exclusive licensee to sue Genetics for infringing the '008 patent.

This syllogism is wrong at every step. Rather than exceeding the scope of the patent, exclusive licenses such as Ortho's are within the scope of the patent grant. But even licenses that exceed the scope of the patent grant are enforceable against third-party infringers absent proof that they unreasonably restrain competition in a relevant market. Even if there were such proof -- and there is none here -- it would not bear upon the exclusivity of Ortho's license or on Ortho's standing to sue.

The district court's decision is unprecedented as well as illogical. The court below acknowledged that "[t]he parties do not cite, and this Court has not found, any case" in which an exclusive licensee was denied standing because restrictions in its license exceed the scope of the patent. (Op. at 21). The

decision below is the first -- and only -- decision adopting this theory.

SUMMARY OF ARGUMENT

The district court denied Ortho standing on the erroneous grounds that a field-of-use restriction in Ortho's license supposedly "exceeds the scope of the patent." According to the district court, a field-of-use license to use a patented invention in the U.S. to make an unpatented product for sale outside the U.S. "exceeds the scope of the patent" and, "as a matter of law," the holder of such a license lacks standing to sue for infringement in its licensed field.

Under settled law, however, the holder of an exclusive license to use a patented invention in a particular field-of-use has standing to sue third parties who commit acts of infringement in the licensed field. As the holder of an exclusive license to use the patented inventions in the U.S. to make EPO for sale outside the U.S., Ortho unquestionably meets this test. (Point I).

Moreover, the use restrictions in Ortho's license do not provide a basis for denying Ortho standing. Those restrictions are reasonably within the scope of the patent grant -- but even if they exceeded it, that would not make Ortho's rights unenforceable in the absence of proof that the license unreasonably restrains competition in a relevant market. There is no evidence in this record that could support such a conclusion. (Point II).

Even more basically, the entire issue of whether the license restriction "exceeds the scope of the patent" does not have any bearing on Ortho's standing. It is not the measure of whether Ortho's license is "exclusive" or whether Ortho has

standing to sue. (Point III).

In addition, Ortho's standing is confirmed by sections of the License Agreement that discuss infringement actions against third parties. (Point IV).

Finally, the district court had subject matter jurisdiction over Ortho's infringement claim (Point V), and lawsuits pending in California and in Germany do not provide a basis for dismissal of this action. (Point VI).

POINT I

ORTHO HAS STANDING TO SUE FOR INFRINGEMENT IN THE LIMITED AREA OF ITS EXCLUSIVE USE LICENSE

The district court recognized the established principles that govern licensee standing -- but then failed to apply them.

A. The Applicable Legal Standards

It is basic law that the holder of an exclusive license has standing to sue for infringement in its exclusive licensed field. See Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459, 467-68 (1926). As the district court recognized:

> "An exclusive licensee generally has standing to sue for infringement against anyone operating without authority in the stated area of exclusivity." 6 Chisum, Patents, § 21.03[2][c] at 21-157 (1991).

(Op. at 11). Numerous cases recognize the standing of an

exclusive licensee to sue for infringement.[1]

The rationale for conferring standing on exclusive licensees was explained in Philadelphia Brief Case Co. v. Specialty Leather Products Co., 145 F. Supp. 425, 428, 111 USPQ 180, 182 (D.N.J. 1956), aff'd, 242 F.2d 511 (3d Cir. 1957):

> [S]ince the creation of such rights in the so-called exclusive licensee, impliedly, if not

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[1] See, e.g., Kalman v. Berlyn Corp., 914 F.2d 1473, 1481-82, 16 USPQ 2d 1093, 1099 (Fed. Cir. 1990); Weinar v. Rollform, Inc., 744 F.2d 797, 807, 223 USPQ 369, 374 (Fed. Cir. 1984), cert. denied, 470 U.S. 1084 (1985); Solarex Corp. v. Arco Solar, Inc., 805 F. Supp. 252, 257 (D. Del. 1992) ("An exclusive licensee ... has standing to sue for infringement against those operating within the scope of exclusivity without authority."); Calgon Corp. v. Nalco Chemical Co., 726 F. Supp. 983, 986, 13 USPQ 2d 1529, 1531 (D. Del. 1989); Dreamlite Holdings, Ltd. v. Kraser, 705 F. Supp. 98, 101, 9 USPQ 2d 1401, 1403 (E.D.N.Y. 1988), aff'd, 878 F.2d 1446 (Fed. Cir. 1989); Darda, Inc. USA v. Majorette Toys (U.S.) Inc., 627 F. Supp. 1121, 229 USPQ 103 (S.D. Fla. 1986), aff'd in part and rev'd in part on other grounds, 824 F.2d 976 (Fed. Cir. 1987); Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc., 565 F. Supp. 931, 220 USPQ 416 (D.N.J. 1983); Brunswick Corp. v. United States, 22 Cl. Ct. 278, 19 USPQ 2d 1702 (Ct. Cl. 1991); Pratt & Whitney Co. v. United States, 153 F. Supp. 409, 114 USPQ 246 (Ct. Cl. 1957).

> expressly, prevents the proprietary owner of the patent from creating further rights therein in unknown third parties, this so-called exclusive licensee, while only a licensee, comes so close to having truly proprietary interests in the patent, that the courts have held that he is equitably entitled to sue on the patent . . . .

To be "exclusive" for standing purposes, a license need not cover all of the rights conferred by the patent. As the district court itself recognized, "an exclusive license can be created by a grant of exclusivity based solely upon geographic, time, or field-of-use limitations." (Op. at 13). Thus, standing has been sustained where the relevant license covers only the right to sell, e.g., Weinar v. Rollform, Inc., 744 F.2d at 807, 223 USPQ at 374; or a limited geographic territory, e.g., Green v. Le Clair, 24 F.2d 74 (7th Cir. 1928); or a limited field-of-use, e.g., Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc., 222 USPQ 143 (D. Kan. 1983) (veterinary field only), Pratt & Whitney Co. v. United States, 153 F. Supp. 409, 114 USPQ 246 (use with engines in aircraft and guided missiles only); or the right to sell only to a particular customer, Brunswick Corp. v. United States, 22 Cl. Ct. 278, 19 USPQ 2d 1702 (sale to U.S. government only). In Independent Wireless, 269 U.S. 459, an exclusive license to use the patented invention only for commercial radio purposes conferred standing.

It is also not necessary for standing that the license be exclusive as against the patent owner. As the district court "stressed," the "test for exclusivity is . . . whether the licensor has promised explicitly or implicitly not to grant additional licenses to third parties." (Op. at 13). See, Western Electric Co. v. Pacent Reproducer Corp., 42 F.2d 116, 120 (2d Cir.), cert. denied, 282 U.S. 873 (1930); Research Frontiers, Inc. v. Marks Polarized Corp., 290 F. Supp. 725, 727, 160 USPQ

574, 575 (E.D.N.Y. 1968); Wing Engineering Corp. v. United States, 151 F. Supp. 314, 315, 113 USPQ 343 (Ct. Cl. 1957).

B. Ortho Has an Exclusive License In a Limited Field-of-Use

Ortho has standing as an exclusive licensee under the settled principles summarized above.

As the district court recognized, the License Agreements grant Ortho "'an exclusive license' to use the inventions claimed in the '008 patent for the manufacture of EPO in one location in the U.S. . . . for use and sale outside the U.S. (excluding China and Japan)." (Op. at 18). (See A 628-29; A 144-45). The district court also recognized that the License Agreements "clearly" preclude Amgen from granting additional licenses in Ortho's exclusive licensed field. (Op. at 18).

As the holder of an exclusive license in a limited field-of-use, Ortho plainly has standing to sue for acts of infringement in its exclusive licensed field. Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. at 467-68.

C. Genetics' Infringement Took Place in Ortho's Exclusive Licensed Field

It already has been adjudicated that Genetics infringed the '008 patent. Amgen, 927 F.2d 1200, 18 USPQ 2d 1016. What is more, Genetics' infringing acts took place in Ortho's exclusive licensed field. (A 194).

Genetics admits that its infringing acts consisted of using the '008 inventions in the United States to make EPO for

sale abroad by its European licensee, Boehringer. (A 194). The district court found that Boehringer has paid Genetics $34,100,000 for the EPO that Genetics produced by its acts of infringement. (Op. at 6).

By its acts of infringement, Genetics appropriated a right that Amgen had licensed exclusively to Ortho, i.e., the right to use the patented inventions in the U.S. to make EPO for sale outside the U.S. (A 628-29, A 144-45). Ortho has standing as an exclusive licensee to sue Genetics for its infringement in Ortho's licensed field.

POINT IV

PARAGRAPH 8.02 OF THE LICENSE AGREEMENTS CONFIRMS ORTHO'S RIGHT TO SUE FOR INFRINGEMENT IN ITS LIMITED FIELD-OF-USE

Paragraph 8.02 of the License Agreements confirms Ortho's standing to sue for infringement in its licensed field. That paragraph recognizes Ortho's rights to sue third-party infringers and "to join AMGEN" in an infringement action. (A 651, A 171). It also requires Amgen to "execute all papers and to perform such other acts as may be reasonably required" to assist Ortho in that endeavor. (Id.)

Ortho tried to exercise its contractual rights under paragraph 8.02 in March 1989, when it moved to intervene in the Amgen action. (A 234). However, Amgen opposed Ortho's motion to intervene. (A 409). Significantly, in opposing Ortho's motion to intervene, neither Amgen nor Genetics argued that Ortho lacked standing to sue for infringement. Instead, Amgen argued that it could adequately repre-

sent Ortho's interests in the liability phase. (A 415-16).

When Amgen opposed Ortho's motion to intervene, it breached its contractual obligation under paragraph 8.02 to assist Ortho in its efforts to join Amgen in an infringement action. Having previously breached its obligation to cooperate in Ortho's efforts to intervene in the Amgen case, Amgen cannot claim that Ortho now lacks standing to bring its own suit naming Amgen as an involuntary party.

In the court below, Amgen and Genetics cited a clause in paragraph 8.02 which recognizes that Amgen has the "right, but not the obligation, to bring, defend and maintain any appropriate suit or action." (A 651, A 171). They argued that this clause should be read as a matter of law to preclude Ortho from suing.

The district court expressly declined to reach this argument (Op. at 25, n.16 [sic]), and it has no merit. While paragraph 8.02 reserves Amgen's right to sue for infringement, it does not make that right Amgen's alone.

Brunswick Corp. v. United States, 22 Cl. Ct. 278, 19 USPQ 2d 1702 (Ct. Cl. 1991), is on point here. Under the license agreement in Brunswick, the licensor "retain[ed] its right to bring suit for infringement . . . and to recover damages therefor . . ." Id., 22 Cl. Ct. at 280, 19 USPQ 2d at 1705. In moving to dismiss an action brought by an exclusive licensee, the defendant argued that the agreement entitled only the licensor to sue for damages. The Court of Claims disagreed. It held that the "critical point" was that the licensor "merely retained its right to sue . . . and [that] the Agreement does not preclude [the exclusive licensee] from bringing suit." Id., 22 Cl. Ct. at 282, 19 USPQ 2d at 1705 (emphasis in original). This holding is applicable here.

CONCLUSION

For the reasons set forth above, this Court should reverse the Judgment dismissing Ortho's complaint for lack of standing.

Dated: March 23, 1993

Respectfully submitted,

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